

**IN THE MATTER OF  
NON-PRIMARY PERCUTANEOUS  
CORONARY INTERVENTION  
RESEARCH WAIVER REVIEW**

**Anne Arundel Medical Center  
Docket No. 08-02-0032 NPRW**

**Baltimore Washington Medical Center  
Docket No. 08-02-0029 NPRW**

**Holy Cross Hospital  
Docket No. 08-15-0033 NPRW**

**Johns Hopkins Bayview Medical Center  
Docket No. 08-24-0030 NPRW**

**St. Agnes Hospital  
Docket No. 08-24-0028 NPRW**

**Shady Grove Adventist Hospital  
Docket No. 08-15-0027 NPRW**

**Southern Maryland Hospital Center  
Docket No. 08-16-0031 NPRW**

**BEFORE THE MARYLAND  
HEALTH CARE COMMISSION**

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**PARTIAL FINAL DECISION**

**September 18, 2008**

## Table of Contents

|   | Page       |
|---|------------|
| <b>I. Introduction .....</b>  | <b>1</b>   |
| State Health Plan: Cardiac Surgery and Percutaneous Coronary Intervention Services .....                | 1          |
| C-PORT Non-primary Angioplasty Study Summary and Status .....   | 2          |
| <b>II. Background .....</b>   | <b>4</b>   |
| Applicant Hospital Attributes .....   | 4          |
| Cardiac Care Quality Measures .....   | 7          |
| <b>III. Application Review and Analysis .....</b>   | <b>11</b>  |
| <b>A. Requirements to be Considered for an npPCI Research Waiver.....</b>                               | <b>11</b>  |
| Study Site Inclusion Criteria .....   | 11         |
| Patient Prioritization Plan .....   | 11         |
| Written Agreement With Tertiary Center .....  | 15         |
| Air or Ground Ambulance Within 30 Minutes .....   | 19         |
| Minimum of 3 Interventional Cardiologists .....   | 20         |
| Physician Criteria.....   | 23         |
| Physicians On-Site Within 30 Minutes When On-Call .....   | 29         |
| Device Selection Criteria .....   | 31         |
| Minimum Volumes in Year 1 and Year 2.....   | 32         |
| 98% Follow-Up Commitment.....   | 43         |
| <b>B. Additional Factors Considered .....</b>   | <b>51</b>  |
| Potential to Improve Geographical Distribution of Cardiovascular Services.....                          | 51         |
| Potential to Increase Access to PCI Services for Minorities and Medically Underserved Populations ..... | 67         |
| Ability and Commitment to Serve as Research Site .....  | 81         |
| Demonstration of Successful and Timely Acquisition of Follow-up Data on Primary PCI Patients.....       | 89         |
| Current Performance Under pPCI Waiver .....   | 93         |
| Provision of Data to the Commission .....   | 96         |
| <b>Summary and Recommendation.....</b>  | <b>99</b>  |
| <b>Executive Director's Recommendation .....</b>  | <b>100</b> |

## List of Tables

|          |  |    |
|----------|--|----|
| Table 1  | Number of Hospitals Participating in the C-PORT E Study as of May 22, 2008.....  | 3  |
| Table 2  | Applicant Hospitals – Licensed Beds and Emergency Department Spaces With Cardiac Monitoring Capability, Number of Hours on Red Alert, and Hospital Utilization.....  | 5  |
| Table 3  | Percent of Acute Myocardial Infarction Patients Receiving Appropriate Care at Applicant Hospitals, April 2006 through March 2007 .....   | 9  |
| Table 4  | Percent of Heart Failure Patients Receiving Appropriate Care at Applicant Hospitals, April 2006 through March 2007 .....   | 10 |
| Table 5  | Number and Regular Business Hours of CCLs at Applicant Hospitals.....  | 15 |
| Table 6  | Applicant Hospitals’ Agreements With Tertiary Care Centers and Medical Transport Service Companies for Care of Patients Enrolled in the C-PORT E Study.....  | 18 |
| Table 7  | Current and Projected (Total) Staffing of PCI Services at Applicant Hospitals.....   | 23 |
| Table 8  | Fellowship Status, On-Call Service, and Cumulative Number of PCI Procedures of Physicians Currently Providing pPCI Services at Applicant Hospitals .....   | 28 |
| Table 9  | Number of Ischemic Heart Disease (IHD) Patients Who Were Discharged From Applicant Hospitals to an Acute Care Hospital .....   | 38 |
| Table 10 | Number of Ischemic Heart Disease (IHD) Patients Who Received Cardiac Catheterization at the Applicant Hospitals and Were Discharged to an Acute Care Hospital.....   | 38 |
| Table 11 | Applicant Hospitals’ Total PCI Volume Based on Data from the Maryland STEMI Registry and Maryland Hospital Data Sets, and Threshold Volume Based on Documented Change in Referral Patterns .....   | 39 |
| Table 12 | Applicant Hospitals’ Plans to Obtain Follow-Up Data on Study Participants .....  | 49 |
| Table 13 | Jurisdictions Served, and Nearest Open Heart Surgical and Applicant Hospitals to Each Applicant.....   | 58 |
| Table 14 | Straight Line Distances (Miles) Between Applicant Hospitals (Blue) and Open Heart Surgical Hospitals in the Metropolitan Baltimore and Metropolitan Washington Regional Service Areas (White-Maryland; Yellow – Washington, DC), and Other Regional Service Areas (Salmon) in Maryland .....       | 59 |
| Table 15 | Non-Rush Hour Driving Times (Minutes) Between Applicant Hospitals (Blue) and Open Heart Surgical Hospitals in the Metropolitan Baltimore and Metropolitan Washington Regional Service Areas (White-Maryland; Yellow – Washington, DC), and Other Regional Service Areas (Salmon) in Maryland ..... | 60 |
| Table 16 | Rush Hour Driving Times (Minutes) Between Applicant Hospitals (Blue) and Open Heart Surgical Hospitals in the Metropolitan Baltimore and Metropolitan Washington Regional Service Areas (White-Maryland; Yellow – Washington, DC), and Other Regional Service Areas (Salmon) in Maryland .....     | 61 |
| Table 17 | Certified and Accredited Cardiovascular Programs at Applicant Hospitals.....   | 66 |
| Table 18 | Current (2007) and Projected (2012) Total Population and Population by Race And Ethnicity (Hispanic) Within Each Applicant’s Primary (PSA) and Extended (ESA) Service Area .....   | 76 |

|          |  |     |
|----------|--|-----|
| Table 19 | Number of Inpatients with Cardiovascular-related Principal Diagnoses and Payer Source in Calendar Year 2006 at Applicant Hospitals. The Percentage (%) of Cardiac Care Patients by Payer Source, Race, and Ethnicity is Based on the Total Number of Cardiac Care Patients at Each Respective Hospital ..... | 78  |
| Table 20 | Percent Service Area Minority Population, Percent Cardiovascular Minority Inpatients, and Ratio of Cardiovascular Minority Inpatients to Service Area Minority Population to Cardiovascular Minority Inpatients .....  | 80  |
| Table 21 | Summary of Research Structure and Oversight and Recent Clinical Research Experience of Applicant Hospitals.....  | 87  |
| Table 22 | Percent of pPCI Patients at Applicant Hospitals for Whom Six-Week Follow-up Data were Obtained.....  | 92  |
| Table 23 | Number of Registrants, STEMI Patients, Ineligible Patients, Cardiac Catheterized (Cathed) Patients, and pPCI Procedures in 2006 and 2007 At Applicant Hospitals.....   | 95  |
| Table 24 | Incidence and Cumulative Duration (Hours) of Equipment- and Staff-Related Down Time at Each Applicant Hospital Since it Applied to Renew its pPCI Waiver.....  | 97  |
| Table 25 | Changes and/or Upgrades of Cardiac Catheterization Laboratory Equipment at Each Applicant Hospital Since It Applied to Renew its pPCI Waiver .....   | 98  |
| Table 26 | Summary of COMAR 10.24.05 Requirements.....  | 103 |
| Table 27 | Summary of COMAR 10.24.05 Additional Factors Considered .....  | 104 |

## **APPENDIX**

### **List of Maps**

|       |   |
|-------|---|
| Map 1 | Locations of Primary Percutaneous Coronary Intervention (pPCI) Programs at Maryland Hospitals Without On-Site Cardiac Surgery and of Maryland and Washington, D.C. Hospitals With Adult Cardiac Surgery Programs (May 2008) |
| Map 2 | Primary and Extended Service Areas of Anne Arundel Medical Center Based on Calendar Year 2006 Cardiovascular Inpatient Discharges   |
| Map 3 | Primary and Extended Service Area of Baltimore Washington Medical Center Based on Calendar Year 2006 Cardiovascular Inpatient Discharges  |
| Map 4 | Primary and Extended Service Areas of Holy Cross Hospital Based on Calendar Year 2006 Cardiovascular Inpatient Discharges   |
| Map 5 | Primary and Extended Service Areas of Johns Hopkins Bayview Medical Center Based on Calendar Year 2006 Cardiovascular Inpatient Discharges  |
| Map 6 | Primary and Extended Service Areas of Shady Grove Adventist Hospital Based on Calendar Year 2006 Cardiovascular Inpatient Discharges  |
| Map 7 | Primary and Extended Service Areas of Southern Maryland Hospital Center Based on Calendar Year 2006 Cardiovascular Inpatient Discharges   |
| Map 8 | Primary and Extended Service Areas of St. Agnes Hospital Based on Calendar Year 2006 Cardiovascular Inpatient Discharges  |

## **I. INTRODUCTION**

On February 4, 2008, the Maryland Health Care Commission received applications from seven community hospitals for a waiver to provide non-primary (elective) percutaneous coronary intervention (npPCI) services as part of a study of the safety and effectiveness of such procedures when performed in hospitals without on-site cardiac surgery. Applications were received from Anne Arundel Medical Center (AAMC), Baltimore Washington Medical Center (BWMC), Johns Hopkins Bayview Medical Center (JHBMC), and St. Agnes Hospital (SAH) in the Metropolitan Baltimore Regional Service Area, and Holy Cross Hospital (HCH), Shady Grove Adventist Hospital (SGAH), and Southern Maryland Hospital Center (SMHC) in the Metropolitan Washington Regional Service Area.

### **State Health Plan: Cardiac Surgery and Percutaneous Coronary Intervention Services**

In Maryland, cardiac surgery and percutaneous coronary intervention (PCI) are governed by State Health Plan chapter COMAR 10.24.17 (the “Chapter”). Policy 5.0 of the Chapter restricts the provision of PCI services to hospitals with on-site cardiac surgical backup, except as provided for by Policies 5.1 and 5.3. Policy 5.1 allows hospitals without on-site cardiac surgical backup that meet requirements set forth in COMAR 10.24.17, Table A-1, to obtain a waiver to perform primary (emergency) PCI. The Commission’s primary PCI (pPCI) waiver program began in 2006. Currently, 13 Maryland hospitals without on-site cardiac surgical backup have waivers to perform pPCI; all but one (Carroll Hospital Center) have active programs (Map 1). Ten Maryland hospitals provide both pPCI and non-primary (elective) PCI in conjunction with on-site cardiac surgery programs (Map 1).

Policy 5.3 empowers the Commission to grant waivers to hospitals without on-site cardiac surgery to participate in research studies that “advance the understanding of how cardiac care services should be organized to improve outcomes.” The Chapter recognizes the need for research to assess the safety and efficacy of elective (non-primary) PCI services among defined patient groups when performed in hospitals without on-site cardiac surgery. Policy 5.3 also requires the appointment of a Research Proposal Review Committee to advise the Commission on research proposals requesting a waiver under the Chapter.

In 2005, the Commission received a proposal from the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) to engage Maryland hospitals without on-site cardiac surgery in a research study of the safety and efficacy of non-primary PCI (npPCI) performed in such facilities. The Commission convened a Research Proposal Review Committee comprised of cardiologists, epidemiologists, and others, drawn from Maryland as well as other states, to review the proposal. Coincident with the completion of the Committee’s work,<sup>1</sup> the investigators withdrew the proposal.

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<sup>1</sup> Maryland Health Care Commission. Report of the Research Proposal Review Committee – Review of the Scientific Merit of the Atlantic C-PORT Trial: Proposed Non-Primary Percutaneous Coronary Intervention (PCI) Study, Version 2.5, March 22, 2005. Baltimore, MD, August 16, 2005.

The C-PORT group submitted a revised proposal to the Commission in 2006, which was reviewed by the reconstituted Research Proposal Review Committee. The Committee found the proposal to be scientifically acceptable, but expressed reservations about the expected rates of patient retention and adverse events, and the potential for patient selection or other bias to be introduced into the study.<sup>2</sup> The Executive Director of the Commission, upon review of the Committee's report, recommended the establishment of a waiver program that would permit Maryland hospitals without on-site cardiac surgery to participate in the study under the Commission's oversight.<sup>3</sup>

The Commission accepted the Executive Director's recommendations on April 19, 2007, and directed Commission staff to draft regulations to implement the recommendations. On August 3, 2007, the Commission proposed new regulations, COMAR 10.24.05, to establish a waiver program under which Maryland hospitals without on-site cardiac surgery could apply to participate in the C-PORT non-primary angioplasty research study (C-PORT E). The regulations established a comparative review process for granting time-limited waivers to a limited number of hospitals meeting specific eligibility requirements, and criteria for both maintaining and relinquishing granted waivers. COMAR 10.24.05 became effective on October 22, 2007.

COMAR 10.24.05.02 establishes a one-time process by which a licensed acute general hospital without on-site cardiac surgery backup may seek a research waiver to provide npPCI services as part of the C-PORT E study; provides for the granting of research waivers to no more than six hospitals; and establishes a comparative review process to identify those applicants that are best qualified to contribute to the success of the study.

### **C-PORT Non-primary Angioplasty Study Summary and Status**

The C-PORT E study will compare the outcomes of npPCI procedures performed in hospitals without on-site cardiac surgery to the outcomes of those performed in hospitals with on-site cardiac surgery. Designed as a non-inferiority clinical trial, the study tests the hypothesis that mortality at six weeks and MACE (major adverse cardiac events, i.e., death, myocardial infarction and/or target vessel revascularization) at nine months post-procedure do not differ between hospitals with and without on-site cardiac surgery. In order for the hypothesis to be accepted, non-inferiority must be demonstrated with regard to both mortality and MACE.

Because of the type of study design employed and clinically-based assumptions about expected mortality and MACE event rates, a total of 16,356 patients who meet strictly defined eligibility criteria are required for the successful completion of the study. Of this number, 75% will receive npPCI at hospitals without on-site cardiac surgery. The other 25% will be randomly assigned to receive npPCI at hospitals with on-site cardiac surgery. Consequently, the study, which began in June 2006, is recruiting patients from multiple hospitals in multiple states. The

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<sup>2</sup> Maryland Health Care Commission. Research Proposal Review Committee – Report 2: Scientific Review of the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) Proposed Non-Primary Percutaneous Coronary Intervention (PCI) Study, Version 3.0, March 29, 2006. Baltimore, MD, March 30, 2007.

<sup>3</sup> Maryland Health Care Commission. Executive Director's Recommendation: Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) Proposal to Study Non-Primary (Elective) PCI Performed in Maryland Hospitals Without On-Site Cardiac Surgery. Baltimore, MD, April 13, 2007.

study includes hospitals in both urban and non-urban areas that represent diverse patient populations, patient volumes, and varying proximities to tertiary care centers.

Patient recruitment for the C-PORT E study began at a single hospital in Alabama on September 2, 2005.<sup>4</sup> As of May 22, 2008, 35 hospitals in nine states had enrolled 6,531 patients in the study.<sup>5</sup> The greatest numbers of participating hospitals are in Georgia (10), New Jersey (9), and Ohio (6) (Table 1). Through May 22, 2008, a total of 28,273 patients had been invited to participate in the study with 26,280 (93%) giving consent and 1,993 (7%) declining to enroll. Of those giving consent, 6,531 (24.9%) have been randomly assigned to undergo npPCI in accord with the study protocol. If the average patient recruitment rate continues, at 121 patients/hospital/year for the 31 hospitals currently enrolling patients in the study, the study is expected to be completed in late 2010; however, if more hospitals participate, the study will be completed sooner. According to the study's Principal Investigator, efforts are being made to engage additional hospitals, including those in Maryland and South Carolina.

**Table 1. Number of Hospitals Participating in the C-PORT E Study as of May 22, 2008.**

| <b>State</b>      | <b>Number of Hospitals</b> | <b>State</b>        | <b>Number of Hospitals</b> |
|-------------------|----------------------------|---------------------|----------------------------|
| <b>Alabama</b>    | 1                          | <b>Ohio</b>         | 6                          |
| <b>Georgia</b>    | 10                         | <b>Oregon</b>       | 1                          |
| <b>Illinois</b>   | 2                          | <b>Pennsylvania</b> | 2                          |
| <b>New Jersey</b> | 9                          | <b>Total</b>        | 31                         |

One of the key requirements for hospitals that participate in the C-PORT E study is to obtain six-week and nine-month follow-up on all enrolled patients. This is difficult to achieve in practice and requires a substantial commitment of resources to institute timely and comprehensive follow-up strategies. The design of the study and its successful completion is predicated on having a complete set of follow-up data for each of the 16,356 patients to be enrolled in the study. Consequently, the study protocol provides that a hospital's participation will be suspended if the delayed data entry rate exceeds 5%; a hospital's participation may be terminated if the data completion failure rate (including lost to follow-up) exceeds 1%.

Since the research project began in 2005, five hospitals have been suspended from the study, four for submitting late or incomplete data and one for randomizing an ineligible patient. All suspensions lasted between three and five days. As of May 22, 2008, the C-PORT E study team had not terminated participation by any hospital.

<sup>4</sup> Information about the status of the study as of May 22, 2008 was provided by the Principal Investigator, Thomas Aversano, M.D. on May 27, 2008.

<sup>5</sup> Two sites in Texas withdrew from the study, one because of insufficient patient volumes and the other because it began offering cardiac surgical services. Two sites in North Carolina withdrew because of insufficient volume. These four sites had enrolled a total of 96 patients in the study.

## **II. BACKGROUND**

The Commission received letters of intent from seven hospitals located in the Metropolitan Baltimore and Metropolitan Washington Regional Service Areas. Anne Arundel Medical Center (AAMC), Baltimore Washington Medical Center (BWMC), Johns Hopkins Bayview Medical Center (JHBMC), and St. Agnes Hospital (SAH) are in the Metropolitan Baltimore Regional Service Area; and Holy Cross Hospital (HCH), Shady Grove Adventist Hospital (SGAH), and Southern Maryland Hospital Center (SMHC) are in the Metropolitan Washington Regional Service Area. All submitted applications on or before the February 4, 2008 filing deadline.

Commission staff reviewed the applications for completeness and on February 22, 2008, AAMC, BWMC, HCH, JHBMC, SMHC, and SAH were notified in writing that the respective applications were incomplete; the SGAH application was determined to be complete as submitted. All six submitted the additional requested information on or before March 7, 2008 as specified by the Commission staff. The seven applications were docketed for review, and public notice was published in the *Maryland Register* on March 28, 2008. Staff requested additional information from all applicants on July 17, 2008; each responded on or before August 1, 2008. The Commission notified all applicants on August 8, 2008 that the record in this matter would be closed and additional information submitted after 4:30 p.m. on August 11, 2008 would not be considered in the review.

### **Applicant Hospital Attributes**

Four of the applicant hospitals are in the Metropolitan Baltimore Regional Service Area. AAMC is a 278 bed facility located at 2001 Medical Parkway in Annapolis, Anne Arundel County. BWMC has 293 beds and is also located in Anne Arundel County at 301 Hospital Drive, Glen Burnie. Both JHBMC and SAH are located in Baltimore City. JHBMC has 333 beds and is located at 4940 Eastern Avenue; SAH at 900 Caton Avenue has 314 beds. Three applicants are in the Metropolitan Washington Regional Service Area. HCH is located in Montgomery County at 1500 Forest Glen Avenue, Silver Spring and has 404 beds. SGAH, also in Montgomery County, has 275 beds and is located at 9901 Medical Center Drive, Rockville. SMHC is a 258 bed facility in Prince George's County at 7503 Surratts Road, Clinton. Four of the applicants, BWMC, HCH, JHBMC, and SAH, are teaching hospitals. Licensed bed capacity, emergency department characteristics, and utilization data for each applicant are presented in Table 2.



**Table 2. Applicant Hospitals - Licensed Beds and Emergency Department Spaces with Cardiac Monitoring Capability, Number of Hours on Red Alert,\* and Hospital Utilization.**

|   | Metropolitan Baltimore Regional Service Area |                 |        |        | Metropolitan Washington Regional Service Area |        |        |
|---|--|-----------------|--------|--------|---|--------|--------|
|   | AAMC   | BWMC            | JHBMC  | SAH    | HCH   | SGAH   | SMHC   |
| <b>Licensed Beds<sup>1</sup></b>        |  |                 |        |        |   |        |        |
| <b>Total MSGA</b>                       | 232  | 274             | 298    | 269    | 294   | 212    | 196    |
| <b>Medical Surgical ICU</b>             | 20   | 12              | 30     | 16     | 30  | 28     | 15     |
| <b>Coronary Care Unit**</b>             | 0  | 12              | 12     | 12     | 12  | 0      | 15     |
| <b>Monitored***</b>                     | 215  | 126             | 126    | 89     | 106   | 185    | 133    |
| <b>Emergency Department (ED)</b>        |  |                 |        |        |   |        |        |
| <b>Total Spaces<sup>2</sup></b>         | 44   | 57              | 39     | 53     | 54  | 56     | 28     |
| <b>Monitored Spaces<sup>2</sup></b>     | 30   | 52 <sup>A</sup> | 22     | 41     | 24  | 30     | 28     |
| <b>Red Alert Hours<sup>3</sup></b>      |  |                 |        |        |   |        |        |
| <b>2007</b>                             | 134.6  | 199.6           | 211.9  | 288.5  | 1599.8  | 1179.2 | 21.6   |
| <b>2008 (Jan 1-June 30)</b>             | 44.1   | 151.5           | 5.7    | 241.3  | 560.1   | 8.5    | 5.8    |
| <b>Utilization</b>                      |  |                 |        |        |   |        |        |
| <b>Inpatient Discharges<sup>4</sup></b> | 28,169                                       | 18,214          | 36,506 | 23,136 | 24,337  | 19,488 | 22,499 |
| <b>ED Encounters<sup>5</sup></b>        | 59,860                                       | 71,127          | 58,891 | 41,165 | 65,107  | 47,642 | 65,237 |

\* A Red Alert occurs when a hospital has no inpatient ECG monitored beds available. These ECG monitored beds include all inpatient critical care areas as well as telemetry beds.

\*\* A hospital may combine the coronary care unit with the intensive care unit to form a critical care unit. In their applications, both AAMC and SGAH referred to the use of a critical care unit.

\*\*\* Monitored means that hard-wired cardiac monitoring is available for the reported number of licensed beds.

<sup>1</sup> Source: Maryland Health Care Commission, Acute Care Hospital Inventory, FY 2009. Bed use: MSGA = medical, surgical, gynecological, addictions; ICU = intensive care unit

<sup>2</sup> Source: Maryland Health Care Commission, Acute Care Hospital Inventory, FY 2009 Supplemental Emergency Department Survey, June 1, 2008

<sup>3</sup> Source: Maryland Institute for Emergency Medical Services Systems, County/Hospital Alert Tracking System, Alert Summaries, Regions III and V, January 1 through December 31, 2007 and January 1 through June 30, 2008, <http://www.miemss.org/HospitalAlert/ReportChatsRegion.asp>, accessed March 19 and July 21, 2008

<sup>4</sup> Source: Health Services Cost Review Commission, Maryland Hospital Discharge Data Set, July 1, 2006 through June 30, 2007

<sup>5</sup> Source: Health Services Cost Review Commission, Maryland Hospital Ambulatory Care Data Set, July 1, 2006 through June 30, 2007

<sup>A</sup> Includes 29 acute treatment spaces and 23 non-acute treatment spaces

During calendar year 2007 and the first half of 2008, there was considerable variability in the amount of time each applicant's emergency department was on red alert.<sup>6</sup> During 2007,

<sup>6</sup> According to the Maryland Institute of Emergency Medical Service Systems in MIEMSS Region III, which approximates the MHCC Metropolitan Baltimore Regional Service Area, a red alert is declared when a hospital has no ECG monitored beds available. These ECG monitored beds include all in-patient critical care areas and telemetry beds. The facility will receive unstable (Priority I) monitored patients from within its catchment area for initial stabilization. (It is advisable for this facility to be bypassed if another facility that is clear is only 2 to 3 minutes further.) Subsequent transfer to another facility for admission to a monitored bed may be necessary. Priority II & III

cumulative red alert hours ranged from 21.6 hours (less than one day) at SMHC to 1179.2 hours (49.1 days) at SGAH, and 1599.8 hours (66.7 days) at HCH. The other applicants were on red alert for 288.5 hours (12 days) or less. From January 1 through June 30, 2008, red alert times ranged from fewer than six hours (JHBMC and SMHC) to 560 hours (HCH). SGAH appears on track to experience a dramatic reduction in red alert hours between 2007 and 2008.<sup>7</sup> HCH reduced its red alert hours by nearly two-thirds; however, the hospital's red alert hours remain highest among the applicant hospitals.

The Maryland Institute for Emergency Medical Services Systems (MIEMSS) anticipates designating Acute Cardiac Intervention Centers in 2008. The Maryland Medical Protocols for Emergency Medical Services Providers define a patient with ST-elevation myocardial infarction as a priority I patient. Under the Alert Status System, a red alert would be overridden for a priority I monitored patient, and the patient would be transported to the closest Acute Cardiac Intervention Center or next closest appropriate hospital according to the protocols.

Practice standards for hospital ECG monitoring recommend varying hours of ECG monitoring for patients who have undergone non-urgent (i.e., not for acute MI) PCIs with complications (e.g., 24 hours or longer) and those without complications (e.g., 6 to 8 hours with stenting; 12 to 24 hours without stenting).<sup>8</sup> The C-PORT protocol requires hospitals to identify the post-procedure care area for npPCI patients as part of a development program estimated to require a three-month (or less) effort.

According to information provided by the applicants, each hospital was in compliance with the conditions of participation in Medicare, and the accreditation criteria of the Joint Commission at the time of application, February 4, 2008. St. Agnes Hospital, which had two periods of less than full accreditation by the Joint Commission in 2006 and 2007, reports that the reasons for the hospital's rating as conditionally accredited and provisionally accredited are unrelated to cardiovascular services.

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ECG monitored patients will normally bypass unless transport time will be lengthened by more than 15 minutes, as may frequently occur in more rural areas. In MIEMSS Region V, which approximates the MHCC Metropolitan Washington Regional Service Area, a red alert is declared when a hospital has no ECG monitored beds available and requests that patients who are likely to require this type of care not be transported to their facility. ECG monitored bed is defined as any adult in-patient critical care bed, including specialty critical care units and telemetry beds. The hospital requests that all priority II and III ECG monitored patients are transported to the next closest appropriate hospital. Sources: MIEMSS Region II Alert Status System, Revised July 27, 2005 and MIEMSS Region V Alert Status System, Approved January 28, 1999, Amended November 16, 2000, Corrected January 16, 2001.

<sup>7</sup> The Commission approved a Certificate of Need Application (Docket No. 04-15-2138) on February 16, 2005 that permitted SGAH to undertake an expansion and renovation project, which included increasing its emergency department capacity from 49 to 69 beds, which included 10 monitorable adult beds. Phase 2 of the project, which included emergency department expansion, was completed by April 22, 2008. The expansion of the SGAH emergency department and the expansion of its inpatient bed capacity as a result of the project likely contributed to the marked reduction in red alert hours at the hospital.

<sup>8</sup> Drew BJ, Califf RM, Funk M, et al. Practice Standards for Electrocardiographic Monitoring in Hospital Settings: An American Heart Association Scientific Statement From the Councils on Cardiovascular Nursing, Clinical Cardiology, and Cardiovascular Disease in the Young: Endorsed by the International Society of Computerized Electrocardiology and the American Association of Critical-Care Nurses. *Circulation* 2004;110:2721-2746.

## Cardiac Care Quality Measures

As part of its Hospital Performance Evaluation Guide, the Commission gathers and reports information that comparatively evaluates quality-of-care outcomes and performance measurements for hospitals in the State. This performance measurement system is intended to improve the quality of care by establishing a common set of performance measurements and disseminating the findings of the evaluation. The outcome and performance data for each hospital is reported by the hospitals to the Centers for Medicare and Medicaid Services (CMS) and is publicly available (<http://www.hospitalcompare.hhs.gov>). Reporting hospitals use CMS's definitions to identify eligible patients. For a given condition, a hospital may submit data for all eligible patients; or, if the hospital has more than a specified number of eligible patients, it may submit data for a random sample of patients based on a formula. CMS audits the quality data by reabstracting the data from the medical records for a sample of five Medicare patients per calendar quarter for each hospital.<sup>9</sup>

Maryland hospitals began collecting Appropriate Care Measures (ACM) data for acute myocardial infarction (AMI) and for heart failure (HF) patients on October 1, 2003. The data are for adult patients, including those who do not have Medicare benefits as well as those who do. The ACM data reflect how often a hospital provides recommended care for AMI (six measures) and HF (four measures). The core measures include rates of inpatient mortality among patients with AMI; however, the Commission currently does not publicly report these data.

The following core measures are collected for patients hospitalized with AMI without treatment-specific contraindications:

- Administration of aspirin within 24 hours before or after hospital arrival;
- Administration of beta blocker within 24 hours of hospital arrival;
- Aspirin prescribed at discharge;
- Beta blocker prescribed at discharge;
- Administration of angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) for left ventricular systolic dysfunction (LVSD); and
- Provision of smoking cessation advice/counseling to AMI patients.

Core measures collected for HF patients without treatment-specific contraindications are:

- Administration of angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) for left ventricular systolic dysfunction (LVSD);
- Evaluation of patient for left ventricular systolic function;
- Provision of instructions to HF patients on discharge; and
- Provision of smoking cessation advice/counseling to HF patients.

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<sup>9</sup> U.S. Government Accountability Office. Hospital Quality Data: CMS Needs More Rigorous Methods to Ensure Reliability of Publicly Released Data, GAO-06-54. January 2006.

When compared with the average for all reporting hospitals in the United States, a higher percentage of patients in Maryland hospitals received the recommended care with one exception – ACE inhibitor or ARB administration for AMI was equal to the national average (Tables 3 and 4). SMHC lagged behind the U.S. rate in the administration of aspirin and beta blocker at discharge; HCH, in administration of beta blocker on arrival; and SGAH and JHBMC, in administration of ACE inhibitor or ARB. Both HCH and SMHC had too few eligible AMI patients to reliably predict their performance relative to ACE inhibitor/ARB administration and smoking cessation guidance. All but HCH and SAH exceeded the national average for providing discharge instructions to HF patients; SAH trailed the U.S. rate in administration of ACE inhibitor/ARB to HF patients.

**Table 3. Percent\* of Acute Myocardial Infarction Patients Receiving Appropriate Care at Applicant Hospitals, April 2006 through March 2007.**

| Administration of Aspirin on Arrival      |                 |                        | Administration of Aspirin at Discharge      |                 |                        |
|---|-----------------|------------------------|---|-----------------|------------------------|
| Hospital                                  | Number Eligible | Percent Receiving Care | Hospital                                    | Number          | Percent Receiving Care |
| AAMC                                      | 227             | 100                    | AAMC  | 211             | 100                    |
| BWMC                                      | 174             | 98                     | BWMC  | 95              | 99                     |
| JHBMC                                     | 202             | 98                     | JHBMC                                       | 138             | 99                     |
| SGAH                                      | 192             | 98                     | SAH   | 114             | 99                     |
| <b>Maryland</b>                           | -               | <b>96</b>              | SGAH  | 131             | 96                     |
| SMHC                                      | 159             | 96                     | <b>Maryland</b>                             | -               | <b>95</b>              |
| HCH                                       | 126             | 95                     | HCH   | 74              | 92                     |
| <b>U.S.</b>                               | -               | <b>93</b>              | <b>U.S.</b>                                 | -               | <b>90</b>              |
| SAH                                       | 159             | 93                     | SMHC  | 91              | 87 <sup>A</sup>        |
| Administration of Beta Blocker on Arrival |                 |                        | Administration of Beta Blocker at Discharge |                 |                        |
| AAMC                                      | 228             | 98                     | AAMC  | 216             | 99                     |
| JHBMC                                     | 180             | 98                     | BWMC  | 106             | 99                     |
| BWMC                                      | 153             | 97                     | JHBMC                                       | 143             | 99                     |
| SGAH                                      | 176             | 94                     | SAH   | 135             | 99                     |
| <b>Maryland</b>                           | -               | <b>93</b>              | SGAH  | 132             | 98                     |
| SMHC                                      | 132             | 93 <sup>A</sup>        | <b>Maryland</b>                             | -               | <b>94</b>              |
| SAH                                       | 153             | 89                     | HCH   | 74              | 92                     |
| <b>U.S.</b>                               | -               | <b>88</b>              | <b>U.S.</b>                                 | -               | <b>90</b>              |
| HCH                                       | 85              | 87                     | SMHC  | 98              | 89 <sup>A</sup>        |
| Administration of ACE Inhibitor / ARB     |                 |                        | Smoking Cessation Advice / Counseling       |                 |                        |
| AAMC                                      | 38              | 97                     | BWMC  | 33              | 100                    |
| BWMC                                      | 29              | 93                     | SGAH  | 34              | 100                    |
| HCH                                       | 16 <sup>B</sup> | 89                     | SMHC  | 23 <sup>B</sup> | 100 <sup>A</sup>       |
| SAH                                       | 43              | 88                     | AAMC  | 57              | 98                     |
| <b>Maryland</b>                           | -               | <b>84</b>              | SAH   | 48              | 98                     |
| <b>U.S.</b>                               | -               | <b>84</b>              | <b>Maryland</b>                             | -               | <b>95</b>              |
| SGAH                                      | 29              | 83                     | JHBMC                                       | 55              | 93                     |
| JHBMC                                     | 49              | 78                     | <b>U.S.</b>                                 | -               | <b>90</b>              |
| SMHC                                      | 13 <sup>B</sup> | 77 <sup>A</sup>        | HCH   | 13 <sup>B</sup> | 69                     |

\* Percentages based only on those patients whose history and condition indicate that the treatment is appropriate (number eligible).

Source: [www.hospitalcompare.hhs.gov/Hospital/Search/Tables.asp](http://www.hospitalcompare.hhs.gov/Hospital/Search/Tables.asp) and [www.hospitalcompare.hhs.gov/Hospital/Search/Results.asp](http://www.hospitalcompare.hhs.gov/Hospital/Search/Results.asp) - accessed February 14 and March 19, 2008

<sup>A</sup> Hospital indicated that the submission was based on a sample of its relevant discharges

<sup>B</sup> Number is too small (<25) for purposes of reliably predicting the hospital's performance

**Table 4. Percent\* of Heart Failure Patients Receiving Appropriate Care at Applicant Hospitals, April 2006 through March 2007.**

| Left Ventricular Systolic Function Evaluation |                 |                        | Discharge Instructions                |        |                        |
|---|-----------------|------------------------|---------------------------------------|--------|------------------------|
| Hospital                                      | Number Eligible | Percent Receiving Care | Hospital                              | Number | Percent Receiving Care |
| BWMC  | 802             | 98                     | SGAH                                  | 232    | 94                     |
| SGAH  | 307             | 98                     | BWMC                                  | 638    | 87                     |
| AAMC  | 426             | 96                     | AAMC                                  | 343    | 77                     |
| SAH   | 614             | 95 <sup>A</sup>        | <b>Maryland</b>                       | -      | <b>74</b>              |
| JHBMC   | 630             | 94                     | JHBMC                                 | 498    | 73                     |
| <b>Maryland</b>                               | -               | <b>93</b>              | SMHC                                  | 564    | 72 <sup>A</sup>        |
| HCH   | 353             | 92 <sup>A</sup>        | <b>U.S.</b>                           | -      | <b>65</b>              |
| SMHC  | 620             | 89 <sup>A</sup>        | HCH                                   | 272    | 62 <sup>A</sup>        |
| <b>U.S.</b>                                   | -               | <b>85</b>              | SAH                                   | 469    | 48 <sup>A</sup>        |
| Administration of ACE Inhibitor / ARB         |                 |                        | Smoking Cessation Advice / Counseling |        |                        |
| HCH   | 129             | 95 <sup>A</sup>        | SGAH                                  | 35     | 100                    |
| AAMC  | 187             | 91                     | BWMC                                  | 147    | 99                     |
| BWMC  | 273             | 88                     | SMHC                                  | 127    | 99 <sup>A</sup>        |
| SGAH  | 104             | 88                     | SAH                                   | 107    | 99 <sup>A</sup>        |
| <b>Maryland</b>                               | -               | <b>87</b>              | HCH                                   | 40     | 98 <sup>A</sup>        |
| JHBMC   | 252             | 87                     | <b>Maryland</b>                       | -      | <b>95</b>              |
| SMHC  | 209             | 87 <sup>A</sup>        | AAMC                                  | 50     | 94                     |
| <b>U.S.</b>                                   | -               | <b>83</b>              | JHBMC                                 | 141    | 92                     |
| SAH   | 271             | 82 <sup>A</sup>        | <b>U.S.</b>                           | -      | <b>85</b>              |

\* Percentages based only on those patients whose history and condition indicate that the treatment is appropriate (number eligible).

Source: [www.hospitalcompare.hhs.gov/Hospital/Search/Tables.asp](http://www.hospitalcompare.hhs.gov/Hospital/Search/Tables.asp) and

[www.hospitalcompare.hhs.gov/Hospital/Search/Results.asp](http://www.hospitalcompare.hhs.gov/Hospital/Search/Results.asp) - accessed February 14 and March 19, 2008

<sup>A</sup> Hospital indicated that the submission was based on a sample of its relevant discharges

One study of the relationship between a hospital's performance on the process measures included in Hospital Compare and its mortality rates concluded that "[h]ospital performance measures predict small differences in hospital risk-adjusted mortality rates. Efforts should be made to develop performance measures that are tightly linked to patient outcomes."<sup>10</sup> For discussion of a performance measure that is tightly linked to patient outcomes in primary PCI procedures, see discussion of the applicants' current performance under their pPCI waivers, particularly door-to-balloon time.

<sup>10</sup> Werner RM, Bradlow ET. Relationship between Medicare's Hospital Compare performance measures and mortality rates. JAMA 2006;296:2694-2702.

### III. APPLICATION REVIEW AND ANALYSIS

COMAR 10.24.05.04A(2) establishes review criteria for the evaluation of applications from hospitals seeking a waiver to perform npPCI procedures as part of the C-PORT E study. Each applicant must meet these requirements in order to be considered for an npPCI waiver. In addition, COMAR 10.24.05.04A(3) provides that the Commission shall consider other matters, including five specific factors, in determining whether to grant waiver applications. These additional factors are intended to be used to distinguish among applicants that meet the requirements of Regulation .04A(2) in deciding which of the qualified applicants should be granted npPCI waivers.

#### A. REQUIREMENTS TO BE CONSIDERED FOR AN npPCI RESEARCH WAIVER

**COMAR 10.24.05.04A(1):** *An applicant shall meet the study site inclusion criteria established in the Atlantic C-PORT research study protocol.*

During the development of these regulations, the Commission noted the substantial commitment of staff, financial, and other resources that a hospital would need to make in order to participate in the study. Because participation in the study is contingent upon receiving a research waiver, it was deemed imprudent to expect a hospital to invest the necessary resources to meet the study's inclusion criteria before applying for one of a limited number of waivers. Consequently, the C-PORT E Principal Investigator sent a letter to the president/CEO of each applicant hospital delineating the commitments each would be expected to make if it received a waiver from the Commission to participate in the study.

#### Responses of Applicants

The president and/or CEO of each applicant hospital signed the C-PORT E letter acknowledging the hospital's receipt and acceptance of the requirements that the hospital and staff must meet in order to participate in the study if granted a research waiver.

#### Analysis and Findings

Based on the assurances in these letters, each applicant complies with this requirement.

**COMAR 10.24.05.04A(2)(a)(i):** *An applicant shall provide a patient prioritization plan that guarantees that a patient who requires primary PCI for STEMI is given immediate preference for care in the cardiac catheterization laboratory.*

The purpose of COMAR 10.24.05.04A(2)(a)(i) is to ensure that each applicant considers how participation in the C-PORT E study might affect its ability to provide timely pPCI services during routine business hours when diagnostic cardiac catheterization and npPCI procedures are in progress or scheduled. Numerous studies have demonstrated that pPCI is most beneficial to patients when performed promptly after the initial STEMI diagnosis. The current practice guidelines of the American College of Cardiology/American Heart Association recommend that this emergency procedure be completed within 90 minutes of diagnosis. Under the

Commission's pPCI waiver policy (COMAR 10.24.17, Table A-1), hospitals are required to complete 80% of the procedures in 120 minutes or less. Consequently, applicants were asked to address room use and staffing conflicts that might delay treatment of pPCI patients.

### Responses of Applicants

#### AAMC

AAMC stated that its Guidelines for Primary Percutaneous Intervention Patient Accessibility with Implementation of Non-Primary Percutaneous Coronary Intervention will ensure that a patient requiring pPCI will have immediate access to the cardiac catheterization laboratory (CCL). The hospital has two rooms that are equipped to perform PCI procedures, with appropriate staff on-site from 0700 until 1730, Monday through Friday and on-call at all other times. A cardiology interventionalist is always on-call to perform pPCI.

AAMC employs a block scheduling system to manage and control patient throughput to ensure that npPCI procedures scheduled for the two CCLs do not overlap. The hospital describes five scenarios that reflect various situations that might arise if a pPCI patient presents when both CCLs are in use or are scheduled for use, or when the on-call physician is unavailable. In all cases, a nurse is responsible for coordinating equipment, room, and human resources to provide the best possible care for all patients. AAMC states that any conflicts arising in this process will be resolved by the Clinical and/or Medical Director of the CCL.

#### BWMC

BWMC currently has one cardiac catheterization laboratory in which pPCI is performed; regular hospital business hours are from 0700 until 1700, Monday through Friday. BWMC states that it has adopted a number of procedures to ensure the prioritization of pPCI patients during the six to eight months that it will take the hospital to bring a second cath lab online.

BWMC states that, if a patient is undergoing a procedure in the BWMC CCL when the pPCI team is activated, staff will facilitate the safe completion of the procedure or proceed to a point where the procedure can be halted without harming the patient. If a scheduled procedure has not yet begun when the pPCI activation occurs, the patient's procedure will be delayed or rescheduled. BWMC describes responses to three other scenarios where the CCL is in use or scheduled for an npPCI procedure. If the hospital is unable to accommodate the pPCI patient within 30 minutes, BWMC's tertiary care center partner will be notified and the pPCI patient prepped for transfer or given thrombolytic therapy.

According to BWMC, in the event of bad weather, its CCL staff will maintain regular contact with medical transport providers to determine their ability to arrive and transport npPCI patients in accord with the requirements. If weather conditions are likely to compromise timely patient transport, all npPCI procedures will be rescheduled.



## HCH

HCH has two cardiac catheterization laboratories and has developed a decision tree for ensuring the prioritization of pPCI patients under a variety of scenarios. HCH states that, during regular hospital business hours (0700 until 1730, Monday through Friday), there are sufficient CCL staff in the hospital to simultaneously perform two PCI procedures. According to the decision tree, the hospital has established a mechanism for resolving a variety of room use and staffing conflicts that could arise when a pPCI patient presents.

## JHBMC

JHBMC reports that it has two fully equipped CCLs, one (Room A) is used primarily for diagnostic catheterizations and the other (Room B) for electrophysiologic studies. According to the hospital, during regular business hours (Monday through Friday, 0800 until 1700), there are sufficient qualified physicians, nurses, and technical staff on duty to simultaneously operate both CCLs. Each day, one interventionalist will be designated as the PCI physician of the day (PPD) and will handle all referrals related to both primary and non-primary PCI. A second physician will serve as backup and cover for the PPD if the latter is performing a procedure. Additional physician backup is available daily from Johns Hopkins Hospital (JHH), which is 10 minutes away. JHBMC states that, during regular business hours in 2007, there were no instances when a JHH physician needed to perform pPCI at JHBMC, and there were no instances when a pPCI patient needed to be transferred to another hospital because of CCL or physician unavailability. JHBMC also notes that at least one of three credentialed, non-interventional cardiologists is on duty each business day and is available to perform the diagnostic portion of the catheterization procedure for both pPCI and npPCI while an interventionalist is en route to the hospital.

JHBMC states that its pPCI patient prioritization plan is predicated on timely and effective use of its inter-disciplinary communication system. The effectiveness of this system is reflected in the substantial reduction in pPCI patient door-to-balloon time since the system was implemented in early to mid-2007. The hospital describes three situations in which a pPCI patient presents when both CCLs are in use or scheduled for use. To ensure the timely treatment of the pPCI patient, JHBMC outlines practices for delaying or interrupting scheduled cases if that can be done safely. If a room use or staffing conflict cannot be resolved in a timely manner, the PPD will initiate procedures for transferring the pPCI patient to a tertiary center.

## SGAH

SGAH notes that it has two fully equipped rooms (Labs B and C) in which diagnostic and interventional cardiac procedures are performed. Lab B also is used for vascular diagnostic and intervention procedures, as is Lab A, a diagnostic cath lab. Lab C is used for electrophysiology studies, and Lab B is also used for non-invasive electrophysiology. Cardiac device implants are performed in all three rooms. The hospital maintains 10 pre- and post-procedure beds. SGAH states that, during routine weekday hospital hours of operation (0700 to 1800), two interventional cardiologists are available in-hospital or at nearby practice offices in Rockville and Gaithersburg. A primary and a backup interventionalist are on-call from 1800 until 0700 the next morning on

weekdays and around the clock on Saturdays and Sundays. SGAH states that it has had more than one pPCI patient in the ED at the same time on numerous occasions.

SGAH identified five scenarios in which a pPCI patient presents when one or both of the CCLs is in use. These include both room use and staff availability conflicts. The hospital describes approaches leading to the timely resolution of these conflicts that ensure that the pPCI patient will be given priority for care.

### SMHC

SMHC operates two CCLs and two cardiac catheterization teams are on duty from 0700 until 1700, Monday through Friday. The hospital describes two scenarios in which a pPCI patient presents when both rooms are in use; both involve CCL availability.

### SAH

SAH reports that it maintains two cardiac intervention-capable CCLs and is fully staffed from 0730 until 1700, Monday through Friday; an on-call team provides coverage from 1700 until 0730 the following morning on weekdays and around the clock from 1700 on Friday until 0730 on Monday. Two interventionalists are on-call, one serves as the primary on-call physician for SAH and the other is the designated backup physician for the hospital; the latter may be the primary on-call physician for another hospital. SAH notes that its CCL staff will complete all scheduled procedures each day, even if the work extends beyond the normal close of business; the on-call team is not expected to perform scheduled procedures.

SAH states that it will never simultaneously schedule two npPCI procedures, which will ensure that at least one of the rooms should be available for a pPCI procedure within 20 minutes. The hospital describes two scenarios where a pPCI patient presents when one or both of its procedure rooms are in use.

### Analysis and Findings

All applicants are committed to ensuring that pPCI patients are given priority access to CCLs and qualified staff, and describe two or more scenarios where there are potential conflicts relative to caring for pPCI and npPCI patients. Table 5 summarizes the applicant-provided information with respect to the number of PCI procedure rooms available and the CCL's regular business hours.

HCH provides a decision tree that presents the most comprehensive approach to resolving CCL and staffing conflicts to ensure that pPCI patients receive priority treatment. AAMC, JHBMC, and SGAH describe varying numbers of plausible scenarios involving room access and staffing conflicts. The scenarios described by AAMC, BWMC, and JHBMC consider the possibility of treating the pPCI in-house with thrombolytics or transferring the patient to a tertiary center to reconcile room use and/or staffing conflicts. The scenarios offered by BWMC, SMHC, and SAH are more limited in scope, give more credence to room access than to staffing conflicts, and do not address the simultaneous or near-simultaneous arrival of two pPCI cases.

**Table 5. Number and Regular Business Hours of CCLs at Applicant Hospitals.**

| <b>Hospital</b> | <b>Number of CCLs</b> | <b>Regular Hours (Monday - Friday)</b> |
|-----------------|-----------------------|--|
| AAMC            | 2                     | 0700-1730                              |
| BWMC            | 1                     | 0700-1700                              |
| HCH             | 2                     | 0700-1730                              |
| JHBMC           | 2                     | 0800-1700                              |
| SGAH            | 2                     | 0700-1800                              |
| SMHC            | 2                     | 0700-1700                              |
| SAH             | 2                     | 0730-1700                              |

Based on the submitted patient prioritization plans, each applicant satisfies this criterion.

**COMAR 10.24.05.04A(2)(a)(ii):** *An applicant shall submit a formal and properly executed written agreement with a tertiary care center that provides for the unconditional transfer of each non-primary PCI patient who requires additional care, including emergent or non-primary cardiac surgery or PCI, from the applicant hospital to the tertiary institution.*

#### Responses of Applicants

##### AAMC

AAMC is party to separate formal agreements with Johns Hopkins Hospital and Washington Hospital Center. Each tertiary care center agrees to the unconditional transfer of patients enrolled in the AAMC PCI program for all required additional care, and to provide timely transmission of required follow-up data on transferred patients. In addition, both agree to accept C-PORT E study participants who are randomly assigned to a tertiary facility for npPCI.

##### BWMC

BWMC has a formal and properly executed agreement with the University of Maryland Medical Center (UMMC) providing for the unconditional transfer of patients undergoing cardiac catheterization, pPCI, or npPCI. The agreement also specifies that UMMC will provide timely transmission of required follow-up data on transferred patients. UMMC agrees to accept C-PORT E study participants who are to receive npPCI at a tertiary center under the randomization protocol.

##### HCH

HCH submitted separate, signed agreements with Suburban Hospital and Washington Adventist Hospital, in which each agrees to accept the unconditional transfer of PCI patients from the hospital. Each agrees to timely provide medical and billing data for PCI patients transferred from HCH and to provide npPCI to randomly assigned C-PORT E study participants.

## JHBMC

JHBMC submitted a signed agreement with Johns Hopkins Hospital in which JHH agrees to accept the unconditional transfer of PCI patients from the hospital and to timely provide follow-up data for PCI patients transferred from JHBMC. JHH also agrees to perform npPCI on study participants under the C-PORT E randomization protocol.

## SGAH

SGAH has a formal and properly executed agreement with Washington Adventist Hospital (WAH) providing for the unconditional transfer of patients undergoing cardiac pPCI or npPCI at SGAH. WAH will provide timely transmission of study-required medical and billing data on transferred patients, and will accept patients for npPCI as part of the C-PORT E study.

## SMHC

SMHC submitted a second addendum to the hospital's existing transfer agreement with Washington Hospital Center (WHC) that specifically provides for the unconditional transfer of patients enrolled in the C-PORT E study. The addendum provides that WHC will timely transmit required follow-up data on such transferred patients. WHC also agrees to perform npPCI on C-PORT E study participants randomized to a tertiary center. SMHC subsequently established similar agreements with George Washington University Hospital and Washington Adventist Hospital that provide for the unconditional acceptance of PCI patients, provision of npPCI to randomly assigned participants in the study, and the timely transmittal of follow-up data on those patients.

## SAH

SAH submitted separate, signed agreements with Union Memorial Hospital and St. Joseph Medical Center in which each agrees to accept the unconditional transfer of pPCI and npPCI patients from the hospital. Each agrees to accept study participants randomized to a tertiary facility for npPCI, and to timely provide the required follow-up data.

## Analysis and Findings

All seven applicant hospitals have formal and properly executed agreements with at least one tertiary care center that provides for the unconditional transfer of study patients requiring additional care, e.g., coronary artery bypass grafting, emergent or non-emergent PCI, or other services (Table 6). AAMC, HCH, and SAH each have transfer agreements with two tertiary centers; SMHC has agreements with three. However, having an agreement with a single tertiary center is acceptable under both COMAR 10.24.05 and the C-PORT E study protocol.

In addition, the C-PORT E study protocol requires participating hospitals without on-site cardiac surgical backup to randomly assign one in four study participants to a tertiary care center for npPCI. As part of the research waiver application process, applicants were required to

submit a signed and dated agreement identifying the tertiary center to which study participants will be randomly assigned.

Each applicant has a formal and properly executed agreement with at least one tertiary care center agreeing to accept patients randomly assigned to the center for an npPCI procedure (Table 6). In each case, the randomization agreement was incorporated in or as an addendum to the unconditional transfer agreement. Three of the applicants have agreements to randomly assign patients to either of two tertiary centers; SMHC has agreements with three; the others have agreements to randomize to single centers. Under both COMAR 10.24.05 and the C-PORT E study protocols, a study site is not required to randomize patients to more than one tertiary center.

Each applicant is consistent with this requirement.

**Table 6. Applicant Hospitals' Agreements with Tertiary Care Centers and Medical Transport Service Companies for the Care of Patients Enrolled in the C-PORT E Study.\***

|       | <b>Tertiary Center Accepting Unconditional Transfer of Study Patients Requiring Additional Care</b>  | <b>Medical Transport Service Guaranteeing Ambulance Arrival Within 30 Minutes of Call</b> | <b>Tertiary Center Accepting Patients Assigned Under the Study Randomization Protocol</b>            |
|-------|--|---|--|
| AAMC  | Johns Hopkins Hospital<br>Washington Hospital Center   | Ground - All American Ambulance and Transport   | Johns Hopkins Hospital<br>Washington Hospital Center   |
| BWMC  | University of Maryland Medical Center  | Air & Ground - University of Maryland Expresscare   | University of Maryland Medical Center  |
| HCH   | Suburban Hospital<br>Washington Adventist Hospital   | Air – STAT MedEvac  | Suburban Hospital<br>Washington Adventist Hospital   |
| JHBMC | Johns Hopkins Hospital   | Air & Ground - Johns Hopkins Lifeline, Ground & Air Medical Transportation Services       | Johns Hopkins Hospital   |
| SGAH  | Washington Adventist Hospital  | Ground - All American Ambulance and Transport   | Washington Adventist Hospital  |
| SMHC  | Washington Hospital Center<br>George Washington University Hospital<br>Washington Adventist Hospital | Air - STAT MedEvac;<br>Ground - LifeStar Response   | Washington Hospital Center<br>George Washington University Hospital<br>Washington Adventist Hospital |
| SAH   | Union Memorial Hospital<br>St. Joseph Medical Center   | Ground - LIFESTAR Response of Maryland  | Union Memorial Hospital<br>St. Joseph Medical Center   |

\* The agreements specify that the tertiary center will unconditionally accept study patients who require additional care and will provide npPCI for patients randomly assigned by the study participating hospital. Formal agreements with transport providers guarantee that an ambulance will arrive at the study hospital within 30 minutes of the receipt of the call.

**COMAR 10.24.05.04A(2)(a)(iii): *An applicant must provide documentation that it has an advanced cardiac support emergency medical services provider that guarantees arrival of the air or ground ambulance at the applicant hospital within 30 minutes of a request for non-primary PCI patient transport by the applicant.***

#### Responses of Applicants

##### AAMC

AAMC submitted an agreement with Washington Hospital Center's MedSTAR Transport Service to provide helicopter transport services within 30 minutes of call except under certain conditions, e.g., weather, maintenance-related out-of-service, or multiple calls; this is not consistent with the requirement. In addition, AAMC has an agreement with All American Ambulance and Transport Company that guarantees the arrival of a ground ambulance within 30 minutes of call.

##### BWMC

BWMC has entered into an agreement with University of Maryland Expresscare, a medical transport service providing both air and ground ambulances for the inter-facility transport of both pPCI and npPCI patients. The agreement guarantees the arrival of the ambulance within 30 minutes of receipt of a request for transport of such patients.

##### HCH

HCH has a general air transport agreement with STAT MedEvac that guarantees the arrival of the ambulance within 30 minutes of receipt of a request for transport.

##### JHBMC

JHBMC submitted an addendum to its agreement with The Johns Hopkins Lifeline, Ground & Air Medical Transportation Services that guarantees the arrival of an air or ground ambulance within 30 minutes of receipt of a request for transport of npPCI patients.

##### SGAH

SGAH submitted an agreement with All American Ambulance and Transport Company that guarantees the arrival of a ground ambulance within 30 minutes of call.

##### SMHC

SMHC states that the hospital's existing transport agreements with LifeStar Response (ground ambulance) and STAT MedEvac (air ambulance) apply to patients enrolled in the C-PORT E study. The agreement with each transportation service guarantees ambulance arrival within 30 minutes of a request for patient transport.

## SAH

SAH has entered into an agreement with LIFESTAR Response of Maryland, a medical transport company that provides ground ambulance services, that guarantees the arrival of the ambulance within 30 minutes of receipt of a request for transport of pPCI and npPCI patients.

## Analysis and Findings

All seven applicant hospitals have formal and properly executed agreements with at least one medical transport service that guarantees that an air or ground ambulance will arrive within 30 minutes of receipt of call for the transport of a study participant requiring additional care (Table 6). BWMC, JHBMC, and SMHC have agreements that provide for both ground and air transport that comply with the requirement. The HCH agreement provides only for air ambulance service, and the AAMC, SGAH, and SAH agreements provide only for ground ambulance service; each of these agreements guarantees ambulance arrival within 30 minutes of being called. Both COMAR 10.24.05 and the C-PORT E study protocol requires that an air or ground ambulance must arrive at the study hospital within 30 minutes of request. Each applicant is consistent with this criterion.

**COMAR 10.24.05.04A(2)(b):** *For physician resources, an applicant shall document that it has or will recruit adequate staff necessary for the provision of primary and non-primary PCI services, including a minimum of three interventional cardiologists...*

## Responses of Applicants

### AAMC

AAMC states that current staffing is adequate to accommodate expansion of the hospital's cardiac catheterization services for participation in the C-PORT E study. If the hospital is successful in obtaining an npPCI research waiver, AAMC indicates that Dr. Jonathan Altschuler, who currently performs PCI at both AAMC and Washington Hospital Center (WHC), will no longer schedule interventions at WHC. In addition, the hospital reports that Dr. Robert Lager, another WHC interventionalist, will be reassigned to AAMC if it receives an npPCI research waiver. According to a letter from Dr. Marco Mejia, one of AAMC's current interventionalists, his practice expects to add another interventionalist by August 2009, which would provide the hospital with a fifth interventional cardiologist. The hospital also plans to recruit an additional FTE technologist, and is prepared to add a third cardiac catheterization laboratory, if warranted.

### BWMC

BWMC reports that it has adequate physician, nurse, and technical staff to meet the current volume of pPCI procedures and to begin providing npPCI services. BWMC currently engages four interventionalists to provide pPCI services. A fifth credentialed interventionalist, Dr. Peter Reyes, a faculty member at the University of Maryland School of Medicine, will serve as the on-site co-Principal Investigator for the C-PORT E study and will perform procedures at



BWMC. If granted a waiver, BWMC will recruit and train additional staff concurrent with the addition of a second CCL.

### HCH

HCH indicates that it has adequate physician, nurse, and technical staff to meet the current volume of pPCI procedures and to begin providing npPCI. The hospital states that three interventionalists, Drs. Jack Flyer, Robert Marshall, and Rajendra Shetty, will join the HCH PCI service in September 2008. If granted a research waiver, HCH will recruit and train one additional FTE nurse.

### JHBMC

JHBMC states that it has adequate physician, nurse, and technical staff to meet the current volume of pPCI procedures and to begin providing npPCI. JHBMC will continue its practice of using a bridge team of 16 in-house FTE nurses and 16 in-house FTE radiation technologists to care for STEMI patients while the on-call team is en route to the hospital. This practice will continue if JHBMC receives a research waiver to participate in the C-PORT study. If granted a research waiver, JHBMC will recruit and train one additional FTE nurse and one additional technician.

### SGAH

SGAH reports that it has adequate physician, nurse, and technical staff to meet the current volume of pPCI procedures and to provide npPCI services. Three FTE nurses were added to the CCL staff in September 2007. If the hospital receives a research waiver, staffing ratios, wait times, and turnaround times will be continually monitored to ensure that cardiovascular services are available to all patients in Montgomery County.

### SMHC

SMHC states that it has adequate physician, nurse, and technical staff to meet the current volume of pPCI procedures and to begin providing npPCI. The hospital reports that Dr. Rajendra Shetty, an interventionalist who has diagnostic cardiac catheterization privileges at SMHC is expected to be credentialed to perform PCI at SMHC during the fall of 2008. The hospital states that it also is in discussion with another interventionalist about joining the SMHC PCI service. If granted a waiver, the hospital anticipates recruiting one FTE nurse, and one FTE technician.

### SAH

SAH indicates that it has adequate physician, nurse, and technical staff to meet the current volume of pPCI procedures and to begin providing npPCI. If granted a research waiver, SAH intends to add two FTE nurses, one FTE technician, and one FTE physician assistant; the hospital did not set a time table for the staff increments.

## Analysis and Findings

Table 7 summarizes current and total projected staffing for PCI services at each of the applicant hospitals. All applicants currently have at least the minimum number of physicians necessary to provide pPCI and to initiate an npPCI program if granted a research waiver to participate in the C-PORT study. Under COMAR 10.24.17, a hospital without on-site cardiac surgery must be able to provide pPCI services around the clock, 365 days a year. In order to be able to do so, the regulations also require that a hospital have a minimum of three interventional cardiologists who must participate in the pPCI on-call schedule. The Commission recognizes that a service based on three physicians is less than optimal and may impose excessive demands on physicians and, potentially, may affect the hospital's ability to provide timely and appropriate care to STEMI patients. A three-physician staff results in frequent and/or lengthy on-call assignments, creates challenges if a physician is unexpectedly unavailable for on-call, and limits physician volume relative to both the pPCI program and, potentially, the recruitment of patients for the C-PORT study.

AAMC, HCH, and SMHC report that they currently engage the minimum number of interventionalists as provided for in COMAR 10.24.17; however, all three hospitals have identified additional interventionalists who will join their programs if the hospitals receive npPCI waivers. AAMC has identified a fourth physician who will be added to its PCI services if it receives a waiver; a fifth doctor will be added by August 2009. HCH identified three interventionalists who will join its staff in September 2008. SMHC identified one interventionalist who is expected to receive PCI privileges at the hospital in the fall of 2008 and another who is likely to be credentialed in a similar or slightly longer time frame. BWMC and SGAH both have four interventionalists, while JHBMC (10) and SAH (12) have many more. BWMC intends to engage an additional interventionalist if granted an npPCI research waiver. JHBMC, SGAH, and SAH do not plan to add additional physicians if awarded a research waiver. In addition, BWMC, JHBMC, SMHC, and SAH expect to add both nursing and technical staff if granted a research waiver. SGAH added nursing staff within the past year. AAMC plans to add one technician, HCH will add one nurse, and SAH will add one physician assistant.

Each applicant is consistent with this criterion.

**Table 7. Current and Projected (Total) Staffing of PCI Services at Applicant Hospitals.\***

|       |                        | Date     | Physician       | Nurse (FTE)             | Physician Assistant (FTE) | Technician (FTE)         |
|-------|------------------------|----------|-----------------|-------------------------|---------------------------|--------------------------|
| AAMC  | Current                | 1/08     | 3               | 4.2                     | 0                         | 4                        |
|       | Projected              | 7/08     | 4 <sup>A</sup>  | 4.2                     | 0                         | 5                        |
| BWMC  | Current <sup>B</sup>   | 2/3/08   | 4               | 5                       | 0                         | 2.5                      |
|       | Projected <sup>C</sup> | -        | 5               | 7                       | 0                         | 6                        |
| HCH   | Current                | 2/1/08   | 3               | 3                       | 0                         | 4 (+2 RCIS) <sup>E</sup> |
|       | Projected              | 9/08     | 6 <sup>D</sup>  | 4                       | 0                         | 4(+2 RCIS) <sup>E</sup>  |
| JHBMC | Current                | 7/1/07   | 12 <sup>F</sup> | 4 (+16 BT) <sup>G</sup> | 0                         | 12 (+16 BT) <sup>G</sup> |
|       | Projected              | -        | 12 <sup>F</sup> | 5 (+16 BT) <sup>G</sup> | 0                         | 13 (+16 BT) <sup>G</sup> |
| SGAH  | Current                | 1/15/08  | 4               | 11                      | 0                         | 7                        |
|       | Projected              | -        | 4               | 11                      | 0                         | 7                        |
| SMHC  | Current                | 12/31/07 | 3               | 4 (+2 PRN) <sup>I</sup> | 0                         | 4 (+1 PRN) <sup>I</sup>  |
|       | Projected              | 10/08    | 5 <sup>H</sup>  | 5 (+2 PRN) <sup>I</sup> | 0                         | 5 (+1 PRN) <sup>I</sup>  |
| SAH   | Current                | 2/4/08   | 10              | 6                       | 0                         | 4                        |
|       | Projected              | -        | 10              | 8                       | 1                         | 5                        |

\* Staffing reported as the number of physician interventionalists and the number of nurses, physician assistants, and technicians expressed as full time equivalents (FTEs). Staffing projections are contingent upon receipt of a research waiver, acceptance by C-PORT as a study site, and attainment of study recruitment targets. Projected staffing target dates based on date of application.

<sup>A</sup> AAMC identified a fourth interventionalist who will be added to its PCI service if the hospital receives an npPCI research waiver; another interventionalist is expected to be added to the staff of a hospital-affiliated practice by August 2009

<sup>B</sup> BWMC also engages one supplemental nurse, one supplemental technician, two agency nurses, and two agency technicians to support the pPCI on-call program

<sup>C</sup> Includes one (1) pre/post recovery registered nurse and one (1) pre/post recovery patient care technician

<sup>D</sup> HCH identified three interventionalists who will join the hospital's PCI service in September 2008

<sup>E</sup> Registered Cardiovascular Invasive Specialist

<sup>F</sup> Includes five (5) fellows

<sup>G</sup> Bridge Team – in-house nurses and technicians who care for STEMI patients while awaiting the arrival of the on-call team

<sup>H</sup> SMHC identified one interventionalist who is expected to receive PCI privileges at the hospital during the fall of 2008. Another interventionalist is likely to be credentialed in a similar or slightly longer timeframe.

<sup>I</sup> PRN – position filled as needed with available staff or per diem health care providers

**COMAR 10.24.05.04A(2)(b)(i): [The interventional cardiologists must] meet the requirements in the C-PORT study research protocol and in COMAR 10.24.17, Table A-1;**

Physician inclusion criteria for participation in the C-PORT E study are described in its Manual of Operations (Version 3, March 24, 2006). Several relate to on-site program development, management, and execution. Others are based on the practice guidelines of the American College of Cardiology and the American Heart Association, and are reflected in the physician requirements established by COMAR 10.24.17, Table A-1. Because compliance with

the C-PORT E participation criteria for program development, management, and execution cannot be assessed at this time, the analysis will focus on the requirements in Table A-1:

- Physicians who perform primary PCI should meet the ACC/AHA criteria for competency of 75 or more total PCI cases per year;
- Physicians newly out of fellowship (less than three years) should have completed a minimum of 50 acute MIs during their fellowship training or 10 proctored cases before being allowed to perform primary PCI alone;
- Physicians who perform primary PCI should agree to participate in an on-call schedule; and
- Physicians who perform primary PCI should meet the credentialing criteria for the institution.

### Responses of Applicants

#### AAMC

According to AAMC, physicians meeting its PCI credentialing criteria may perform primary and/or non-primary PCI at the hospital. Three physicians have privileges to perform PCI at AAMC – Drs. Altschuler, Hiatt, and Mejia. All are more than three years out of fellowship, all participate in the hospital's pPCI on-call schedule, and all have privileges at one or more other hospitals. Although not reflected in its written policies, AAMC indicates that interventionalists at the hospital do not simultaneously participate in on-call at two or more hospitals. All three currently credentialed interventionalists at AAMC submitted signed statements agreeing not to participate in simultaneous on-call. Each performed a total of at least 249 PCI procedures annually during calendar years 2006 and 2007. AAMC provided information about Dr. Lager's background and experience, e.g., completed interventional fellowship more than 3 years ago, performed a total of 268 PCI procedures during 2006 and 2007. Already credentialed and on the medical staff at AAMC, he is expected to apply for interventional privileges if the hospital receives a research waiver.

#### BWMC

BWMC indicates that it has five interventional cardiologists (Drs. Miller, Mukherjee, Reyes, Schaeffer, and Yoon), all of whom fulfilled the hospital's credentialing requirements for providing PCI services during 2007 (1) or 2008 (4). Three (Drs. Miller, Mukherjee, and Reyes) are fewer than three years out of fellowship, and each has met the requirements established under COMAR 10.24.17 to be able to perform pPCI alone. Four interventionalists currently participate in BWMC's pPCI on-call schedule. BWMC stated that Dr. Reyes maintains active privileges at BWMC and is currently available for the hospital's program as needed; however, he is not currently a regular participant in the pPCI call schedule. All five physicians signed agreements stating that they will not engage in simultaneous on-call at two or more hospitals if BWMC receives a research waiver. This prohibition will remain in effect for the term of the research waiver. According to BWMC, Dr. Reyes and Dr. Miller completed their fellowships in June 2006 and June 2007, respectively. Based on the 12-month anniversary of fellowship completion, Dr. Reyes exceeded the 75-case requirement. Dr. Reyes will become active in

BWMC's PCI service if the hospital receives an npPCI research waiver. Dr. Miller is on pace to exceed the volume requirement on the 12-month anniversary of the completion of her fellowship. All other BWMC physicians met the requirement based on their average volumes during 2006 and 2007.

### HCH

HCH identified three interventional cardiologists (Drs. Dakak, Kenigsberg, and Woronow), all of whom fulfilled the hospital's credentialing requirements for providing PCI services during 2007 (2) or 2008 (1). All participate in the hospital's pPCI on-call schedule, and have privileges at one or more other hospitals. Each performed, on average, at least 101 PCI procedures annually during calendar years 2006 and 2007. According to the hospital, by practice, HCH interventionalists may serve on-call at more than one hospital, but do not schedule simultaneous on-call. If a physician is simultaneously on-call at more than one hospital, that physician will identify another interventionalist to provide backup coverage and will notify the hospital's Medical Affairs Office of the change. This practice was incorporated into HCH's written policies on March 26, 2008.

The hospital identified three interventionalists who are expected to join HCH's PCI service in September 2008. HCH submitted information regarding the number of PCI procedures performed by one of the physicians from May 1, 2007 to April 30, 2008.

### JHBMC

JHBMC reported having seven interventional cardiologists (Drs. Aversano, Chacko, Miller, Rade, Resar, Thiemann, and Trost), all of whom fulfilled the hospital's credentialing requirements for providing PCI services during 2006 (3) or 2007 (4). Two, Drs. Chacko and Trost, are fewer than three years out of fellowship and each has met the requirements established under COMAR 10.24.17 to be able to perform primary PCI alone. All seven participate in the hospital's pPCI on-call schedule, and have privileges at Johns Hopkins Hospital. Interventional cardiologists at JHBMC are permitted under the hospital's previously submitted written policies to be on-call simultaneously at two or more hospitals. These policies have not changed since 2006 and apply to physicians participating in the hospital's proposed npPCI research program.

According to JHBMC, four of its physicians performed, on average, at least 82 PCI procedures annually during calendar years 2006 and 2007. Dr. Chacko has completed 59 cases between July 1, 2007 when his fellowship ended, and December 31, 2007. Dr. Trost has completed 144 cases since July 1, 2006 when his fellowship ended; he performed 83 procedures during 2007. During calendar years 2006 and 2007, Dr. Aversano averaged 66 procedures annually, with 76 procedures performed during 2007.

### SGAH

SGAH identified four interventional cardiologists (Drs. Chen, Fisher, Friedman, and Kumkumian), all of whom fulfilled the hospital's credentialing requirements for providing PCI services during 2006 (3) or 2007 (1). All participate in the hospital's pPCI on-call schedule;

each has privileges at two or three other hospitals. SGAH states that it prohibits on-call PCI physicians from having simultaneous on-call duties at two or more hospitals. The four physicians performed, on average, at least 95 PCI procedures annually during calendar years 2006 and 2007.

### SMHC

SMHC reported that it has three interventional cardiologists (Drs. Addala, Ashraf, and Leiboff), all of whom fulfilled the hospital's credentialing requirements for providing PCI services during 2006. All participate in the hospital's pPCI on-call schedule, and have privileges at one or more other hospitals. SMHC indicated that it prohibits physicians participating in the hospital's pPCI program from having simultaneous on-call duties at two or more hospitals. Each interventionalist, on average, performed at least 121 PCI procedures annually during calendar years 2006 and 2007.

SMHC identified one interventionalist who is expected to join its PCI service in the fall of 2008 and another who might join the service later in 2008. One physician has privileges to perform diagnostic cardiac catheterization at SMHC; the hospital has not yet granted interventional cardiology privileges to either physician.

### SAH

SAH identified 10 interventional cardiologists (Drs. Albornoz, Cummings, Drossner, DuBois, Mastali, Meilman, Plack, Peichert, Prewitt, and Wang) who will participate in the npPCI program and whose PCI privileges were renewed during 2007. All participate in the hospital's pPCI on-call schedule, and have privileges at four or more other hospitals. According to the hospital, interventional cardiologists are permitted under the hospital's previously submitted written policies to be on-call simultaneously at two or more hospitals. These policies have not changed since 2007 and apply to physicians participating in the hospital's proposed npPCI research program. On average, each physician performed between 120 and 971 PCI procedures annually during calendar years 2006 and 2007.

### Analysis and Findings

Based on hospital-supplied data, all interventionalists identified by AAMC, BWMC, HCH, SGAH, SMHC, and SAH meet the PCI procedure volume requirement specified in COMAR 10.24.17, Table A-1. One physician at JHBMC performed fewer (56) than the required number of procedures (75) during 2006, but performed 76 procedures during 2007. Three hospitals reported having interventionalists who were less than three years out of fellowship: BWMC (3); JHBMC (2); and SAH (2). Each of these hospitals documented that the physicians newly out of fellowship had performed a minimum of 50 AMI cases while a fellow, and/or completed 10 proctored PCI procedures before being allowed to perform the procedure alone.

All of the interventionalists participate or will participate in their hospital's pPCI on-call service. Interventionalists at HCH, JHBMC, and SAH are permitted by hospital policies to be

simultaneously on-call at two or more hospitals. The policies of these hospitals establish mechanisms designed to ensure that a backup on-call physician is available to perform pPCI in the event that the designated on-call physician is unavailable. At SGAH, physicians are prohibited from participating in simultaneous on-call by the hospital's written policy. Simultaneous on-call is not addressed in the hospital policies at AAMC, BWMC, or SMHC; however, the interventionalists who will participate in npPCI programs at those institutions have submitted signed agreements indicating that they will not engage in simultaneous on-call if the hospital receives a research waiver. Table 8 summarizes these findings.

Each applicant is consistent with this criterion.

**Table 8. Fellowship Status, On-call Service, and Cumulative Number of PCI Procedures of Physicians Currently Providing pPCI Services at Applicant Hospitals.**

|       | Number of Physicians | Recent Fellows                    |                                      | All Interventionalists        |                                |                                       | Cumulative Number of PCI Procedures 2006 – 2007* |                   |
|-------|----------------------|-----------------------------------|--------------------------------------|-------------------------------|--------------------------------|---------------------------------------|--|-------------------|
|       |                      | Number <3 Years Out of Fellowship | Number Meeting 10.24.17 Requirements | Number Accepting pPCI On-call | Simultaneous On-Call Permitted | Number Signing Agreement <sup>1</sup> | pPCI   | npPCI             |
| AAMC  | 3                    | 0                                 | -                                    | 3                             | -                              | 3                                     | 404  | 666               |
| BWMC  | 5                    | 3                                 | 3                                    | 5                             | -                              | 5                                     | 199 <sup>A</sup>                                 | 1708 <sup>A</sup> |
| HCH   | 3                    | 0                                 | -                                    | 3                             | Yes                            | -                                     | 608 <sup>B</sup>                                 |                   |
| JHBMC | 7                    | 2                                 | 2                                    | 7                             | Yes                            | -                                     | 281 <sup>C</sup>                                 | 1063 <sup>C</sup> |
| SGAH  | 4                    | 0                                 | -                                    | 4                             | No                             | -                                     | 221  | 883               |
| SMHC  | 3                    | 0                                 | -                                    | 3                             | -                              | 3                                     | 250  | 567               |
| SAH   | 12                   | 2                                 | 2                                    | 12                            | Yes                            | -                                     | 8408 <sup>D</sup>                                |                   |

\* January 1, 2006 through December 31, 2007

<sup>1</sup> Agreement states that the physician will not participate in simultaneous on-call at two or more hospitals if the applicant receives an npPCI research waiver to participate in the C-PORT E study

<sup>A</sup> Number includes post-fellowship volume of one physician, beginning on July 1, 2006; fellowship and, beginning on July 1, 2007, post-fellowship volumes of two physicians.

<sup>B</sup> Hospital cannot distinguish between pPCI and npPCI procedures on the basis of physician records

<sup>C</sup> Number includes post-fellowship volume of one physician, beginning on July 1, 2006; post-fellowship volume of one physician, beginning on July 1, 2007.

<sup>D</sup> Number based on procedures performed by the 10 SAH interventionalists who will participate in the proposed npPCI program



**COMAR 10.24.05.04A(2)(b)(ii): *[The interventional cardiologists must] be available on-site within thirty minutes when on call;***

#### Responses of Applicants

##### AAMC

AAMC indicates that an on-call team is comprised of one physician and at least one nurse and one technician; the fourth team member may be either a nurse or a technician. Each physician is on-call for 24 hours from 0600 until 0600 the following morning, and takes an average of nine call days per month. On-call is equally distributed during weekdays, with rotating call on weekends. Nurses and technicians are on-call 9 to 10 days per month including two weekends; call starts at 1730 on weekdays and ends at 0700 the following morning, and is 24 hours on weekends. AAMC states that all on-call staff members are required to respond by telephone within five minutes of call, and to arrive at the hospital within 30 minutes of call.

##### BWMC

The hospital states that the 5-member BWMC on-call team consists of one physician, two nurses, and one technician; the fifth team member may be a nurse or a technician. Four of the hospital's five physicians equally share on-call responsibilities on a monthly basis; one physician is on-call each evening from 1700 until 0700 the following morning and around the clock on weekends and holidays. Staff nurses and technicians are on-call three to four evenings a week and every other weekend. One supplemental nurse, one supplemental technician, three agency nurses, and two agency technicians also participate in pPCI on-call. On-call hours for nurses and technicians are 0630 to 1700, Monday through Thursday, 1700 Friday through 0700 Saturday, 0700 Saturday through 0700 Sunday, and 0700 Sunday through 0630 Monday; holiday on-call is 24 hours. BWMC reports that all on-call team members are required to arrive at the hospital within 30 minutes of call.

##### HCH

According to HCH, an on-call team consists of one physician, one nurse and two technicians. The hospital's three physicians share on-call responsibilities on a weekly rotation schedule; each physician is on-call around the clock during each on-call week. The hospital is expecting three interventionalists to join its PCI service in September 2008. At that time, each interventionalist will be on-call every sixth week, according to HCH. Nurses rotate on-call service each week and are on-call from 1730 each weekday evening until 0700 the following morning, and around the clock from 0700 Saturday until 0700 Monday. Technicians rotate on-call every other week and follow the same schedule as the nurses. HCH states that all on-call team members are required to arrive at the hospital within 30 minutes of call.

##### JHBMC

The hospital reports that the 5-member JHBMC on-call team consists of one physician, one fellow, one nurse, and two technicians. Physicians are on-call every sixth day for 24 hours;

fellows are on-call for 24 hours every fifth day. Nurses are on-call two to four days each week for 12.5 hours on each on-call day, and are on-call 24 hours a day every fourth weekend. Cardiovascular technicians are on-call one to four days a week and every fifth weekend, while radiology technicians are on-call one day a week and one weekend a month. On-call hours for both the radiology and cardiovascular technicians are identical to those of the nurses. All are required to arrive at the hospital within 30 minutes of page. In addition, JHBMC notes that it has established a “bridge team” of critical care nurses and radiation technologists who are cross-trained to care for critically ill patients in the CCL. The bridge team is mobilized on presentation by a STEMI patient to facilitate the patient’s care and transport to the CCL while the pPCI team is en route to the hospital. Upon arrival of the pPCI team, bridge team members resume their regular duties.

### SGAH

SGAH states that the on-call team consists of one physician, two nurses, and two technicians. Each physician is on-call every fourth day, Monday through Thursday from 1800 until 0700 the next morning, and every fourth weekend, from 1800 Friday until 0700 the following Monday. A backup on-call interventionalist may be called in at the discretion of the primary on-call physician. Nurses are on-call every fourth week from 1730 until 0700 Monday through Thursday, and from 1730 Friday until 0700 on the following Monday. Technicians are on-call every third week and follow the same on-call hours. Both nurses and technicians are on-call around the clock on holidays. SGAH reports that all members of the on-call team are required to arrive at the hospital within 30 minutes of page.

### SMHC

According to the hospital, the pPCI on-call team at SMHC consists of one interventional cardiologist, one nurse, one radiology technician, and two others, who are drawn from the available pool of nurses and technicians. Physicians are on-call 24 hours a day, one to two days per week and every third weekend. Nurses and technicians are on-call on weekdays from 1600 until 0700 the following morning and around the clock on weekends and holidays. SMHC states that staff scheduling of on-call is variable, but that all on-call staff members are required to arrive at the hospital within 30 minutes of page.

### SAH

SAH indicates that an on-call team consists of two physicians, an administrative physician, two nurses, and two technicians. The administrative cardiologist assumes care of the patient immediately, communicates with family members, and cares for the patient until time of discharge. The three physicians and one nurse are on-call every fifth weekday from 1700 until 0800 the following morning, and every fifth weekend from 1700 Friday until 0800 Monday. One nurse is on-call on the same Monday through Thursday schedule and from 1730 on Friday until 0700 on Monday. On weekends, a nurse is in-hospital on Saturday and Sunday from 0700 until 1930, and on-call from 1930 Saturday until 0700 Sunday. Technicians are on-call every fourth weekday and every fourth weekend, and follow the same timing as on-call physicians and nurses. SAH reports that it also engages supplemental nursing and technical staff for on-call

duties who may take call for one week at a time in accord with the above times. All are required to arrive at the hospital within 30 minutes of page.

### Analysis and Findings

Because the life-saving benefits of pPCI are clearly associated with the promptness of the intervention,<sup>11</sup> the Commission requires that the on-call interventionalist must be available on-site within 30 minutes of call, and that 80% of eligible STEMI patients receive the intervention within 120 minutes of arrival.<sup>12</sup> Requiring that the interventionalist arrive within 30 minutes of call is intended to provide sufficient time for the patient to be transported to the CCL, prepared for the procedure, and the procedure to be initiated within the 120-minute window.

All seven applicants have established on-call pPCI teams that support the hospitals' pPCI programs. Although the respective teams differ in size and composition, all of the hospitals require team members to arrive on-site within 30 minutes of page. JHBMC has a bridge team of on-duty staff who provide for in-hospital transport and other aspects of STEMI patient care while awaiting the arrival of on-call staff, which can reduce the time to intervention. Both JHBMC and SAH have large numbers of staff interventionalists, which facilitate the identification of back-up interventionalists for their on-call teams.

Each applicant has identified at least three interventionalists who currently participate in the hospital's primary PCI program and wish to participate in the C-PORT E study. Elective PCI may be scheduled during a physician's on-call hours at the hospital. To ensure that pPCI patients receive timely care, each applicant's on-call policies provide for backup of on-call physicians and staff in the event the team is called while performing an elective procedure.

Each applicant satisfies this criterion.

**COMAR 10.24.05.04A(2)(b)(iii):** *[The interventional cardiologists must] agree to abide by the Device Selection Criteria in the C-PORT study protocol defined in its Manual of Operations;*

### Responses of Applicants

Each of the interventionalists currently credentialed at the applicant hospitals who will participate in the npPCI study submitted a signed statement agreeing to abide by the interventional device selection restrictions imposed by the C-PORT E study protocol.

### Analysis and Findings

All physicians identified by the applicants as the designated interventionalists for the proposed npPCI programs have submitted signed statements agreeing to abide by the C-PORT E study protocol, which prohibits the use of certain interventional devices. The agreements state

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<sup>11</sup> See for example, Nallamothu BK et al., Time to treatment in primary percutaneous coronary intervention. N Eng J Med 2007;357:1631-1638.

<sup>12</sup> For AMI patients who do not have an EKG diagnostic for STEMI at the time of hospital arrival, but remain under observation, the door-to-balloon time clock starts at the time an EKG diagnostic of STEMI is first obtained.

that a physician who uses an unauthorized device must notify the hospital, the C-PORT E Principal Investigator, and the Commission within three business days, and that, upon receipt of written notice from the Commission, the physician will cease participating in the study.

AAMC, HCH, and SMHC identified interventionalists who are expected to join their respective PCI services during the second half of 2008 or in 2009. HCH submitted device agreements sign by three interventionalists who are not currently credentialed at the hospital. Any hospital granted an npPCI research waiver will need to provide credentialing and other information for each interventionalist joining the service in accord with COMAR 10.24.17, Table A-1. Those anticipating participating in the npPCI research study will need to submit a signed device agreement.

Each applicant is consistent with this criterion.

**COMAR 10.24.05.04A(2)(c): *For minimum volumes, an applicant shall document that it will meet and maintain a minimum volume of 100 PCI procedures during the first year of its waiver, and 200 PCI procedures during the second year of its waiver...***

The C-PORT E study of the safety and efficacy of npPCI when performed in hospitals without cardiac surgical backup began in other states in 2006. After diagnostic cardiac catheterization (Dx cath) and prior to patient randomization, specific post-catheterization criteria are used to determine whether the patient is eligible for npPCI under the study protocol. STEMI patients are excluded from the study prior to catheterization; post-catheterization exclusion criteria include the patient's need for coronary artery bypass surgery or if the patient is considered to be at high procedural risk. Based on the experience of hospitals in other states, the C-PORT E Principal Investigator advised the hospitals prior to filing their applications that, on average, 30% of diagnostic catheterizations result in npPCI treatment. In addition, the study protocol requires that participating hospitals randomly assign 25% of eligible patients to tertiary care centers for the intervention. Applicants also were advised to document the number of patients being sent to other facilities for catheterizations and to document anticipated changes in physician referral patterns when assessing the hospital's ability to recruit patients into the study. The information provided by the applicants is described below.

### Responses of Applicants

#### AAMC

AAMC reports that the hospital performed 94 PCI procedures during calendar year 2007. The hospital cites billing data indicating that 331 Dx caths were performed during 2007. This diagnostic cath volume equates to 99 estimated npPCI procedures, with 74 being performed at AAMC and 25 referred to a tertiary center under the study protocol. AAMC's 2007 data suggest that the hospital would be able to perform a total of 168 PCI procedures.

During 2007, AAMC also referred 227 patients to other hospitals for Dx caths according to internal billing data. If these patients had received Dx cath at AAMC and 30% (68) had been eligible for npPCI, the hospital would accrue, after randomization, an additional 51 PCI

procedures. When combined with the above estimate based on catheters performed at AAMC, the hospital estimates that it would perform a total of 219 PCI procedures.

In addition to the inpatient data, AAMC identified 28 outpatients (patients with ischemic heart disease, excluding STEMI, referred out for diagnostic catheterization) who were transferred to other hospitals during 2007 following observation, same-day surgery, or emergency room visits without admission.

AAMC states that the above estimate “does not include data from physician practices in Annapolis that are unable to refer their patients to AAMC for diagnostic catheterizations.” The hospital submitted information based on billing data from Cardiology Associates, P.C., a practice affiliated with AAMC’s pPCI program. During 2007, the practice’s physicians referred 606 patients residing in the hospital’s self-defined service area to other hospitals for Dx cath. Also during 2007, Annapolis Cardiology Consultants referred 89 Dx cath patients to other hospitals who could have been referred to AAMC. The hospital applied the same formula to the practices’ data.

AAMC submitted letters of commitment from the hospital’s Chief and Associate Chief of Cardiology Service, the Chair of Medicine, and several cardiologists to refer npPCI patients to the proposed program. The hospital also submitted a letter of support, signed by 10 physicians affiliated with Cardiology Associates, P.C. A subsequent letter from the practice states that it will “redeploy the necessary physician manpower to guarantee that our patients will be cared for at Anne Arundel Medical Center, and that all of the volume requirements of the npPCI protocol will be met.” The practice expressed an intention to reorient patients that are currently referred from AAMC to Washington Hospital Center (WHC) or George Washington University Hospital as well as patients seen at the practice’s offices in Annapolis, Bowie, and Stevensville (Kent Island, Queen Anne’s County).

The letter from Cardiology Associates states that Dr. Jonathon Altschuler, who currently practices at both AAMC and WHC, will perform all of his interventional procedures at AAMC if the hospital receives a research waiver. Additionally, Dr. Robert Lager, who performs interventional procedures at WHC and is currently on the medical staff at AAMC, will be redeployed to AAMC to perform interventions. A letter from Annapolis Cardiology Consultants indicates that the practice is recruiting an additional interventionalist for the hospital and expects to complete the process by August 2009.

### BWMC

According to BWMC CCL data, its physicians performed 70 pPCI procedures during 2007. Another 16 STEMI patients were seen at the hospital during 2007, but were transferred to the University of Maryland Medical Center (UMMC) because the CCL was closed for renovation for approximately three months. Despite the closure, CCL data indicate that 107 Dx catheters were performed at the hospital. If 30% of these cases had resulted in npPCI, with the hospital retaining 75% of the cases, BWMC states that the hospital would have an estimated PCI volume of 94 (24 npPCIs plus 70 pPCIs).

BWMC cites 2007 internal discharge data indicating that 440 inpatients were transferred to another hospital for Dx cath. Similarly, emergency department transfer logs indicate that 98 cardiac patients were transferred to another hospital during 2007. If these 538 patients had received Dx cath at BWMC, 161 likely would be eligible for npPCI, with 75% (121) receiving the procedure at the hospital. When added to the 2007 data for pPCIs and Dx caths performed at the hospital, the hospital estimates completing a total of 215 procedures.

BWMC states that hospital-affiliated interventional cardiologists performed 913 Dx caths at UMMC and 567 at other hospitals during 2007. If all of the catheterizations performed at UMMC were performed at BWMC, and 30% (274) required npPCI, the hospital estimates that it would complete another 206 interventions after patient randomization.

BWMC submitted supporting correspondence from the two largest cardiology practices at the hospital, representing 14 cardiologists, indicating their support for the hospital's proposed npPCI program and willingness to approach patients about the study. Both practices currently direct npPCI patients to UMMC, which is BWMC's designated tertiary care center partner. Physicians at each practice stated that they will refer npPCI patients to BWMC if the hospital is granted a research waiver: "Given the opportunity to do these [procedures] locally, we are committed to first offering the option of participating in the study to our patients at BWMC."

## HCH

HCH notes that it performed 53 PCI procedures during 2007 according to the Maryland STEMI Registry and 128 Dx caths according to the hospital's CCL procedure log. Based on the 128 Dx caths, the hospital would identify 38 npPCI eligible patients, with 29 (75%) receiving the procedure at HCH. This yields a combined PCI volume of 82 procedures.

According to HCH, its clinical database indicates that during 2007, 134 inpatients with a diagnosis of myocardial infarction were transferred to other hospitals for additional catheterization and staging; this excludes 17 STEMI patients who were transferred to other hospitals. Of the 134 transferred patients, 40 would be expected to qualify for npPCI upon Dx catheterization. If the catheterization and npPCI procedures were performed at HCH, the hospital estimates completing 30 interventions. This would yield a total PCI volume of 112.

Physicians currently participating in the hospital's pPCI program and designated to provide npPCI services at HCH indicated that they will refer eligible patients from their practices to the HCH program. In addition, HCH submitted letters of support from three other interventionalists who are expected to begin providing pPCI services at the hospital in September 2008. Each of the six physicians estimated the number of patients that he annually refers to other hospitals for diagnostic caths. HCH reported that the six physicians "identified a total of 1,508 patients annually who could be asked to participate in Holy Cross Hospital's npPCI research." The hospital also states, "Because this is a research trial and patient consent is imperative, we cannot identify exactly how many patients each physician will refer. However, we believe that when patients are asked by their physician a high percentage will enroll." The hospital applied the percentages for estimating npPCI volume to the total number (1,508).

The Kaiser Permanente Medical Group (Kaiser) advised HCH in writing that the group supports the hospital's participation in the study and, "while it is premature to comment on the number of cases that we would perform at Holy Cross," anticipates that some of the group's patients will opt to have needed coronary interventions performed at HCH. Kaiser gave no indication of how many patients might be involved; however, HCH notes that during FY 2007, the hospital cared for 1,657 Kaiser Permanente cardiac patients.

### JHBMC

JHBMC reported performing 70 PCI procedures and 398 Dx caths during 2007. The 398 Dx caths convert to 119 npPCI procedures that, when adjusted for randomization, would result in 89 procedures being performed at the hospital. This yields an estimated total PCI volume of 159 cases. The hospital also reports that data from the Johns Hopkins Health System database and the Union Memorial Hospital CCL indicate that JHBMC referred 190 patients to these hospitals for Dx cath during 2007. If 30% (57) were found to be npPCI eligible and 75% of those (43) received the procedure at JHBMC, the hospital would have a total PCI volume of 202 cases.

A letter from the Chief, Division of Cardiology at JHBMC states that, subject to the wishes of the patient or the conditions of the patient's insurance, the division "is committed to retaining as medically appropriate 100% of JHBMC patients" if the hospital receives a research waiver to perform npPCI. JHBMC notes that the hospital "has successfully negotiated new third party payor contracts including MAMSI/United Healthcare for the provision of cardiology services."

### SGAH

Citing the Maryland STEMI Registry and hospital data, SGAH states that it performed 95 pPCI procedures and 315 Dx left heart catheterizations during 2007. Based on the number of catheterizations, the hospital estimates that it would identify 95 npPCI eligible patients and, after randomization, SGAH would perform 71 of the npPCI procedures. This yields an estimated total PCI volume of 166 procedures.

According to SGAH's hospital IT system, emergency department transfer log and EMSTAT records, 213 patients with ischemic heart disease were transferred from SGAH to other facilities. SGAH reports that this figure excludes 19 patients transferred due to insurance coverage. If these IHD patients presenting at SGAH remained at the hospital and 30% (64) were npPCI eligible, SGAH might expect to complete 48 of those interventions.

SGAH notes that of the 315 Dx caths performed at SGAH during 2007, the majority (243) were performed by physicians from a single practice, Cardiac Associates. During the same period, this group performed 729 Dx caths at Washington Adventist Hospital (WAH). Cardiac Associates commits to performing 70% of the Dx caths now done at WAH at SGAH. These 510 additional catheterizations would be expected to identify 153 npPCI eligible patients and, after randomization would provide SGAH with an additional 115 procedures.

## SMHC

According to SMHC, its billing data shows that 72 pPCI procedures and 432 Dx cath were performed at SMHC during 2007. If 30% of the diagnostic procedures had resulted in npPCIs performed at the hospital after randomization, SMHC states that the hospital would perform a total of 169 (72 primary + 97 non-primary) PCI procedures.

Based on the billing records of the three physicians who perform pPCI at SMHC, the hospital reports that these physicians transferred 144 patients to other hospitals for Dx cath during 2007. In addition, SMHC notes that a review of transfer summaries identified an additional 25 IHD patients who were transferred to another hospital for catheterization during 2007. Thus, the total number of transfers during 2007 was 169. From this, the hospital anticipates identifying 51 npPCI eligible patients with 38 being randomized to receive the procedure at SMHC. When this figure is added to the 2007 pPCI volume and the number of npPCI procedures, the hospital would be expected to perform based on its 2007 Dx cath volume, SMHC expects to perform a total of 207 PCI procedures.

With regard to expected changes in referral patterns, SMHC submitted a letter from SMHC interventionalist, Dr. Muhammad Ashraf, stating that, based on practice billing records, he performed 104 Dx cath at hospitals other than SMHC during 2007 (total of 107 diagnostic cath at George Washington University Hospital or GWUH, with three transfers from SMHC). Dr. Ashraf estimates that, based on patient hospital preference and excluding patients in need of cardiac surgery, 78 (75%) of those procedures could be done at SMHC. This could result in the identification of 23 npPCI eligible patients and 17 npPCI procedures at the hospital.

Dr. Roy Leiboff, an SMHC interventionalist, submitted a letter to the hospital indicating that physicians in his practice (Heart Center of Southern Maryland, L.L.P.) performed a total of 512 Dx cath during 2007 (44 of the cases were transfers from SMHC to GWUH). When adjusted to account for procedures performed at SMHC and at other hospitals which are not likely to be subject to changes in referral patterns, Dr. Leiboff identified a pool of 201 Dx cath patients. Allowing for patients needing cardiac surgery and those with specific hospital preferences, he estimates that 75% (151) would be referred to SMHC for Dx cath. Of these, the hospital expects to identify 45 npPCI eligible patients and to perform 75% (34) of the procedures.

Similarly, Dr. Srinivas Addala, another SMHC interventionalist, submitted a letter stating that during 2007 he performed 207 Dx cath at WAH on patients not transferred from SMHC (80 were transferred from SMHC to WAH). Using the practice's billing records, Dr. Addala estimates that 60% to 70% of the 207 patients would be referred to SMHC for Dx cath. Thus, SMHC would have 124-145 additional Dx cath. Using the midpoint (134) as the basis for further calculations, the hospital expects to identify 40 npPCI eligible patients and to perform 30 procedures.

In addition, the hospital presented separate letters from five physicians in three group practices and two private practice physicians who perform Dx cath at SMHC indicating that they



will actively recruit patients for the C-PORT E study by seeking patient consent in accord with the study protocols.

## SAH

Citing internal medical records and CCL scheduling records, SAH reported that 78 pPCI procedures and 965 Dx caths were performed during 2007. Based on the Dx cath volume, the hospital identified 290 npPCI eligible patients, with 218 of those receiving the procedure at SAH. When combined with the pPCI volume (78), the hospital estimates a total PCI volume of 296 procedures, enough to exceed the volume requirements.

To supplement the estimated npPCI procedures calculated from its diagnostic cath volume, SAH identified an additional patient group comprised of emergency department and observation patients, and inpatients transferred to tertiary centers for diagnostic and/or interventional procedures because they did not meet the pPCI eligibility criteria and did not receive Dx cath at SAH prior to transfer. Based on internal medical records and billing records from Midatlantic Cardiovascular Associates (MCA), 167 of these patients were transferred during 2007. SAH projects that 30% (50) of these patients would be found to be npPCI eligible on Dx cath and 75% of those (38) would receive the procedure at the hospital.

SAH states that another potential source of patients consists of those that are currently referred to other hospitals by physicians at MCA, a practice co-located on the SAH campus. According to information provided in a letter from the practice, MCA billing data indicate that two of SAH's interventionalists performed 616 Dx caths at other hospitals during 2007. The practice states that after allowing for clinical needs, insurance contracting, and physician coverage, 330 of these procedures would be done at SAH. SAH expects this to result in the identification of 99 npPCI eligible patients, with 74 receiving the intervention at SAH.

## Analysis and Findings

Acute coronary syndrome (ACS) includes myocardial infarction (both STEMI and non-ST-elevation myocardial infarction or NSTEMI) and unstable angina (UA). In the C-PORT npPCI trial, only patients with STEMI are excluded from randomization; the study population includes patients with stable angina, unstable angina, and acute MI. The C-PORT investigators expect that more acute (unstable angina, NSTEMI) and fewer stable patients will be enrolled in the study. Sicker, more unstable patients (i.e., more acute MIs) tend to present at the community hospital. With regard to the management of patients with UA/NSTEMI, national guidelines indicate that, excluding patients who need urgent intervention, coronary angiography to identify the exact location and severity of a patient's coronary artery disease may be used early (i.e., immediately) or deferred (i.e., within a 12- to 48-hour period of time). Patients at high risk for mortality and recurrent ischemia should receive cardiac catheterization and revascularization within 48 hours of presentation. One study, however, found that patients with non-ST-segment elevation acute coronary syndromes who were at high risk for predicted in-hospital mortality frequently did not receive guideline-recommended diagnostic procedures.<sup>13</sup>

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<sup>13</sup> Roe MT, Chen, AY, DeLong ER, et al. Patterns of transfer for patients with non-ST-segment elevation acute coronary syndrome from community to tertiary care hospitals. *Am Heart J* 2008;156:185-92.

Tables 9 and 10 show the breakdown of transferred patients with ischemic heart disease and the number who had cardiac catheterization performed prior to transfer to an acute care hospital. With a few exceptions, these patients were transferred to tertiary hospitals.

**Table 9. Number of Ischemic Heart Disease (IHD)<sup>1</sup> Patients Who Were Discharged from Applicant Hospitals to an Acute Care Hospital<sup>2</sup>: 2007**

| <b>Hospital</b> | <b>Discharges</b>        |                              |                       |                  |                 |              |
|-----------------|--------------------------|------------------------------|-----------------------|------------------|-----------------|--------------|
|                 | <b>STEMI<sup>3</sup></b> | <b>Other AMI<sup>4</sup></b> | <b>UA<sup>5</sup></b> | <b>Other IHD</b> | <b>Subtotal</b> | <b>Total</b> |
| AAMC            | 30                       | 99                           | 50                    | 78               | 227             | 257          |
| BWMC            | 32                       | 113                          | 60                    | 168              | 341             | 373          |
| HCH             | 15                       | 50                           | 16                    | 29               | 95              | 110          |
| JHBMC           | 7                        | 74                           | 2                     | 51               | 127             | 134          |
| SGAH            | 15                       | 75                           | 30                    | 67               | 172             | 187          |
| SMHC            | 14                       | 117                          | 27                    | 57               | 201             | 215          |
| SAH             | 30                       | 55                           | 22                    | 121              | 198             | 228          |
| <b>Total</b>    | <b>143</b>               | <b>583</b>                   | <b>207</b>            | <b>571</b>       | <b>1,361</b>    | <b>1,504</b> |

<sup>1</sup>Ischemic Heart Disease (IHD) - Principal Diagnosis ICD-9 Codes 410-414

<sup>2</sup>Discharge to acute care hospital - Discharge Disposition Code 40

<sup>3</sup>STEMI - 410.01, 410.11, 410.21, 410.31, 410.41, 410.51, 410.61, 410.81

<sup>4</sup>Other AMI: NSTEMI - 410.71; AMI, unspecified site (not otherwise specified) – 410.91

<sup>5</sup>Unstable Angina (UA) - 411.1

**Table 10. Number of Ischemic Heart Disease (IHD)<sup>1</sup> Patients Who Received Cardiac Catheterization at the Applicant Hospitals and Were Discharged to an Acute Care Hospital<sup>2</sup>: 2007**

| <b>Hospital</b> | <b>Discharges</b>        |                              |                       |                  |                 |              |
|-----------------|--------------------------|------------------------------|-----------------------|------------------|-----------------|--------------|
|                 | <b>STEMI<sup>3</sup></b> | <b>Other AMI<sup>4</sup></b> | <b>UA<sup>5</sup></b> | <b>Other IHD</b> | <b>Subtotal</b> | <b>Total</b> |
| AAMC            | 10                       | 8                            | 0                     | 7                | 15              | 25           |
| BWMC            | 17                       | 0                            | 0                     | 1                | 1               | 18           |
| HCH             | 9                        | 7                            | 1                     | 3                | 11              | 20           |
| JHBMC           | 3                        | 49                           | 0                     | 36               | 85              | 88           |
| SGAH            | 7                        | 9                            | 0                     | 16               | 25              | 32           |
| SMHC            | 8                        | 7                            | 2                     | 19               | 28              | 36           |
| SAH             | 25                       | 43                           | 9                     | 90               | 142             | 167          |
| <b>Total</b>    | <b>79</b>                | <b>123</b>                   | <b>12</b>             | <b>172</b>       | <b>307</b>      | <b>386</b>   |

<sup>1</sup>Ischemic Heart Disease (IHD) - Principal Diagnosis ICD-9 Codes 410-414

<sup>2</sup>Discharge to acute care hospital - Discharge Disposition Code 40

<sup>3</sup>STEMI - 410.01, 410.11, 410.21, 410.31, 410.41, 410.51, 410.61, 410.81

<sup>4</sup>Other AMI: NSTEMI - 410.71; AMI, unspecified site (not otherwise specified) – 410.91

<sup>5</sup>Unstable Angina (UA) - 411.1

Except for the patients with a principal diagnosis of STEMI, the C-PORT E study requires participating hospitals to approach all patients coming through the cardiac cath lab about

participation in the study. IHD patients who have been admitted to the hospital represent an important source of potential candidates for the npPCI study.

The Commission requires that a hospital receiving an npPCI research waiver perform a minimum volume of 100 PCI procedures during the first year of its waiver, and 200 PCI procedures during the second year of its waiver. As part of the waiver application, each hospital submitted information addressing how it expects to meet these requirements. Applicants that relied upon changes in physician referral patterns to meet the volume requirements were directed to provide documentation stating quantitatively how those patterns would change.

Table 11 was compiled from 2007 PCI volume and 2006 inpatient and outpatient Dx cath volume (ICD-9 procedure codes 3721, 3722, and 3723; CPT codes 93501, 93510, and 93526; data reporting for the outpatient data sets changed on July 1, 2007) for each of the applicant hospitals. These data were used to estimate the number of patients likely to be eligible for npPCI (i.e., 30% of patients undergoing Dx cath and accounting for 75% of those procedures being performed at the applicant hospital).

**Table 11. Applicant Hospitals' Total PCI Volume Based on Data from the Maryland STEMI Registry and Maryland Hospital Data Sets, and Threshold Volume Based on Documented Change in Referral Patterns.**

|       | PCI<br>Volume<br>Under<br>pPCI<br>Waiver <sup>1</sup> | Dx Cath<br>Cases | Estimated<br>npPCI<br>Volume | npPCI Treatment Site |                    | Total PCI<br>Volume at<br>Applicant<br>Hospital <sup>2</sup> | Total PCI<br>Volume ≥200<br>with<br>Documented<br>Change in<br>Referrals |
|-------|---|------------------|------------------------------|----------------------|--------------------|--|--|
|       |   |                  |                              | Applicant            | Tertiary<br>Center |  |  |
| AAMC  | 94  | 288              | 86                           | 65                   | 21                 | 159  | Yes  |
| BWMC  | 67  | 182              | 55                           | 41                   | 14                 | 108  | No*  |
| HCH   | 53  | 139              | 42                           | 32                   | 10                 | 85   | No   |
| JHBMC | 66  | 391              | 117                          | 88                   | 29                 | 154  | No   |
| SGAH  | 96  | 414              | 124                          | 93                   | 31                 | 189  | Yes  |
| SMHC  | 73  | 563              | 169                          | 127                  | 42                 | 200  | -  |
| SAH   | 77  | 933              | 280                          | 210                  | 70                 | 287  | -  |

Sources: Maryland Health Care Commission, STEMI Registry: preliminary 2007 data, May 17, 2008; Health Services Cost Review Commission, Maryland Hospital Discharge Data Set, CY 2006; Maryland Hospital Ambulatory Surgery Data Set, CY 2006

<sup>1</sup> Audited data were obtained on May 17, 2008, following review by the STEMI Registry Director. The data used by a hospital in its analysis may reflect PCI attempts instead of device uses.

<sup>2</sup> Total PCI cases = number of PCI cases (use of device) in 2007 plus number of estimated npPCI cases

\*Based on the following assumptions, BWMC would likely have the potential to reach the Year 2 volume threshold: minimal CCL downtime; an annual pPCI volume of at least 80; and retention of ≥ 55% of the diagnostic case volume identified as transfers or referrals to UMMC. However, within the existing limitations of the hospital's current CCL structure (i.e., one procedure room), BWMC would lack sufficient capacity to meet the CCL demand generated by both a pPCI and an npPCI program. To address this issue, BWMC has proposed to add a second CCL in six to eight months.

A dash (-) indicates that the hospital has sufficient volume in the absence of any change in referral patterns.

As noted, the method to estimate PCI volume includes a calculation based on diagnostic catheterizations; this analysis does not include coronary angiography identified as inherent to the intervention procedure. Cardiology Associates queried its billing data for diagnostic procedures performed on patients living in the Maryland ZIP codes surrounding the practice's offices in Stevensville, Bowie, and Annapolis. These cases included patients that originated in the hospital (AAMC) and were transferred to a tertiary facility, as well as elective cases that originated from the practice's offices. Cardiology Associates stated its intention to reorient the care of these patients in the future, should AAMC receive a non-primary PCI waiver. Of the 606 diagnostic catheterizations identified, 578 of the cases were in AAMC's PSA or ESA.

Using practice billing data, Annapolis Cardiology Consultants identified 79 diagnostic catheterizations that were "diverted from our primary market to neighboring hospitals in 2007," of which 70 were in AAMC's PSA or ESA. An additional 10 cases were not listed by ZIP code. The practice is "willing to divert portions of those volumes to Anne Arundel Medical Center as appropriate based on patient convenience and willingness to participate in the study." The portion of cases was unspecified.

Using internal billing data, AAMC previously identified 227 inpatient and 28 outpatient cases with ischemic heart disease (IHD) who were transferred to another acute care hospital in 2007. The hospital determined that 17 of the 227 IHD inpatients received a diagnostic catheterization during or within 30 days prior to the hospitalization.<sup>14</sup> The inpatient portion of those caths would be included in the reported 331 inpatient caths done in 2007. The discharge abstract data showed 227 IHD inpatients (excluding STEMI), 15 of whom received cardiac catheterization during hospitalization at AAMC.

An unidentified number of the two physician practices' cases in AAMC's PSA or ESA (648) are included in the hospital's total of 255 patients transferred to another acute care hospital. Based on the number of referrals and the stated intention to change referral patterns of these patients, it is reasonable to expect AAMC to obtain at least an additional 183 diagnostic cases. AAMC is consistent with this requirement.

BWMC is part of the University of Maryland Medical System. Using University of Maryland Medical Center (UMMC) cath lab data, BWMC identified 632 diagnostic catheterizations performed by the four interventionalists who perform 100% of the pPCI procedures at BWMC and have practices at UMMC. The caths performed at UMMC represent transfers to, or direct referrals to, the four cardiologists, who are members of Arundel Heart Associates or the Heart Center of Northern Anne Arundel County. Both groups anticipate that "a significant portion of the patients who currently receive care at UMMC ... will potentially have their procedure done at BWMC." The portion of cases was unspecified. BWMC stated that one

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<sup>14</sup> This analysis was requested of each applicant by the Commission. Specifically, applicants were advised to determine the number of adult (18 years of age and older) inpatient ischemic heart disease (ICD-9-CM codes 410-414) discharges to other acute care hospitals during calendar years 2006 and 2007, and to determine the number of transferees who received Dx catheterization during or just prior to the hospitalization during which the transfer occurred. Patients with a principal diagnosis of STEMI (ICD-9-CM codes 410.01, 410.11, 410.21, 410.31, 410.41, 410.51, 410.61, or 410.81) were excluded.

practice has its only office in BWMC's ZIP code, and the other practice has its main location in the hospital's ZIP code. No data by ZIP code of patient residence were provided.

Based on BWMC discharge data and emergency department transfer logs, the hospital identified 440 admissions and 98 emergency department patients transferred to another hospital for cardiac reasons, including catheterization. Using HSCRC discharge data, BWMC reported that 343 IHD inpatients were transferred in 2007; the vast majority of these patients were transferred to UMMC. Three of the transferred patients received a diagnostic cath during their hospitalization at BWMC.

The Commission notes that the cardiac cath lab at BWMC was closed for 10 weeks in 2007; based on the hospital's prior performance, it is reasonable to expect that BWMC would otherwise have performed pPCI on at least 80 patients (increasing the estimated total PCI volume to at least 121). Among the applicant hospitals, BWMC reported the largest volume of AMI (excluding STEMI) and UA patients transferred to a tertiary facility in 2007; based on the hospital's discharge abstract data, 341 IHD inpatients (excluding STEMI) were transferred, one of whom received a cath during hospitalization. Based on the number of referrals to UMMC and the physicians' stated intention to change referral patterns of these patients, it is reasonable to expect BWMC to obtain at least the lower end of a range of 350 to 410 additional diagnostic cases (approximately 55% of the case volume transferred or referred to UMMC). With one CCL, however, BWMC would be unable to meet the demand generated by both a pPCI and an npPCI program. BWMC is found not to be consistent with this requirement.

In addition to the hospital's three currently participating interventionalists, HCH identified three interventionalists who have agreed to join the npPCI program if the hospital is granted a waiver. Using each physician's estimate of the number of patients annually referred to other hospitals for diagnostic caths, HCH stated that "a total of 1,508 patients annually [who] could be asked to participate in Holy Cross Hospital's npPCI research." In letters of support, two of the current interventionalists have committed to "referring eligible patients ... to the hospital"; the remaining physician expressed "enthusiastic support for the program." These physicians performed slightly less than half of the reported total (n=708). None of the physicians specified the portion of cases that would be expected to be performed at HCH as a result of a change in referral patterns; no data by ZIP code of patient residence were provided. Additionally, members of the Mid-Atlantic Kaiser Permanente Medical Group support the hospital's application; they stated, "While it is premature to comment on the number of cases that we would perform at Holy Cross, [we] anticipate that a number of our patients would opt to have their coronary interventions performed at Holy Cross were this to become an option."

Based on HCH's internal database, the hospital transferred 134 inpatients with a myocardial infarction (excluding STEMI) to another hospital for additional cardiac cath and staging (cath and/or PCI) in 2007. Based on discharge abstract data, the hospital identified 95 IHD patients in 2007 who were transferred to other hospitals; 11 of those patients received Dx cath during their hospitalization at HCH. HCH must retain a high percentage of IHD inpatients to obtain 67 additional diagnostic cases to meet the Year 1 requirement. The hospital did not provide similar data on IHD outpatients transferred from HCH to tertiary hospitals; the inclusion of those cases would have yielded additional volume to meet the Year 1 requirement. Further,

the hospital did not, as instructed, provide an estimate of how many patients each of the current interventionalists would refer to HCH. Nevertheless, it is reasonable to expect that, among these sources, HCH would obtain sufficient volume to meet the Year 1 requirement. However, the documentation provided by HCH does not support an expectation that the hospital will be able to obtain the 510 additional cases needed to meet the Year 2 requirement. HCH is not consistent with this requirement.

Part of the Johns Hopkins Health System (JHHS), JHBMC stated that “a substantial number of Bayview-based patients currently undergo diagnostic catheterization ... at Johns Hopkins Hospital [JHH]. ... A few patients are transferred to other hospitals based on insurance dictates and capitation programs.” Using data from the JHHS Patient Reporting System and data from the Union Memorial Hospital (UMH) cardiac cath lab, JHBMC reported that a total of 190 patients were referred to JHH or UMH for diagnostic catheterization in 2007. The faculty of physicians in the Division of Cardiology at JHBMC expressed a commitment to retain “as medically appropriate 100% of JHBMC patients,” with the exception of referrals to “honor the patient’s wishes [or] comply with the patient’s insurance ...” JHBMC reported that in 2007 there were 189 transfers of IHD NSTEMI patients, with 82 receiving Dx catheterization during their hospitalization at JHBMC. Discharge abstract data indicate that 127 IHD inpatients (excluding STEMI) were discharged from JHBMC to an acute care hospital in 2007; approximately one-third (n=42) did not receive a cardiac cath during their hospitalization at JHBMC. JHBMC must obtain at least an additional 203 diagnostic cases to meet the volume requirement in the second year. The above data do not support the hospital’s meeting this threshold. JHBMC is not consistent with this requirement.

SGAH is part of Adventist HealthCare, which also includes Washington Adventist Hospital. Cardiac Associates stated that the practice “will conservatively commit to performing an additional 510 Diagnostic Cardiac Catheterizations annually at Shady Grove Adventist Hospital. This represents 70% of our current volume at Washington Adventist Hospital. It does not represent additional diagnostic cases being performed [at other hospitals] or our current diagnostic volume at Shady Grove Adventist Hospital.” SGAH used its own discharge (transfer) analysis to determine that 8 of 131 IHD patients transferred in 2007 had diagnostic cardiac catheterizations prior to transfer. Discharge abstract data indicate that more than three-fourths of the 172 IHD inpatients (excluding STEMI) who were discharged from SGAH to an acute care hospital did not receive a cardiac cath during their hospitalization at SGAH in 2007. The above data show that it is reasonable to expect SGAH to obtain an additional 50 diagnostic cases to meet the PCI volume requirements in Year 2. SGAH is consistent with this requirement.

Using physician billing records and transfer summaries for IHD patients who were transferred from SMHC to three tertiary hospitals for diagnostic catheterization, SMHC identified a total of 169 patients. Each of the three interventionalists who currently perform pPCI at SMHC provided estimates of the number of cases that would be expected to be performed at SMHC as a result of a change in referral patterns. The estimates took into account patient preference and categories of patients that would require cardiac surgery. Using billing records, SMHC identified 35 IHD patients (excluding STEMI) who received Dx cath during or just prior to the hospitalization that resulted in their transfer to another acute care hospital. Discharge abstract data indicate that more than three-fourths of the 201 IHD inpatients

(excluding STEMI) who were discharged from SMHC to an acute care hospital did not receive a cardiac cath during their hospitalization at SMHC in 2007. It is reasonable to expect SMHC to exceed the PCI volume requirements. SMHC is consistent with this requirement.

Based on internal data, SAH reports that during 2007 the hospital discharged 257 IHD patients to other acute care hospitals. Of those transferred, 185 received Dx cath during or just prior to the hospitalization during which the transfer occurred. Discharge data show that a high percentage (72%) of IHD patients receive cardiac catheterization at SAH prior to transfer. SAH has sufficient volume in the absence of any change in referral patterns to be able to meet the Year 2 requirement. SAH is consistent with this requirement.

**COMAR 10.24.05.04A(2)(d): *For patient follow-up, an applicant shall commit to meet and maintain a patient follow-up rate of 98 percent for patients enrolled in the C-PORT study.***

#### Responses of Applicants

##### AAMC

AAMC indicates that it has created a new FTE nursing position, Cardiac Program Coordinator (CPC), to establish and maintain liaisons with patients from recruitment through collection of follow-up data. The CPC will facilitate a participant-centered approach to achieve the study's objectives while laying the foundation for ensuring ongoing community support for, and participation in future clinical studies. The CPC will educate and inform patients about the study and participation requirements, review issues related to consent and personal health information, and obtain information and preferences regarding follow-up and alternative follow-up family member contacts.

The CPC will make three attempts by telephone or mail to contact the AAMC patients for each required follow-up. If unsuccessful, the CPC will attempt to reach the patient's designated contacts. A patient who voluntarily withdraws from the study will be contacted by the CPC and a study physician to discuss the effect withdrawal may have on the study and future patient care. Follow-up by telephone will occur at patient-preferred times, including weekends and other non-business hours; as patient volume increases, the CPC will be assisted by other nurses and research staff members.

According to the hospital, a second FTE nurse will serve as the medical data coordinator at AAMC and will coordinate data acquisition from across hospital units, including financial data. The work of the medical data coordinator will be facilitated by a database/repository developed for internal reporting and review by study physicians. Following on-site auditing, the data for AAMC's study enrollees will be transmitted to the Study's Sextant registry. The CPC will be able to use forms and reports created by the AAMC registry to facilitate patient tracking for follow-up, as well as recording follow-up information.

AAMC notes that its study physicians have established professional relationships with their counterparts in tertiary care hospitals to which study patients will be randomized. Through these contacts, AAMC's medical and financial data coordinators will engage their counterparts

and the medical records department at the tertiary center(s) to establish communication lines to assure the timely provision of study-related data. Ideally, as soon as a patient is randomized to a tertiary center, the AAMC coordinators will contact that hospital to ensure that data collection and transmission are expedited. If AAMC's medical data coordinator learns that a study patient has had an encounter at a hospital other than one of the designated tertiary centers, the AAMC financial data coordinator will be notified. Both coordinators will contact their counterparts at that hospital to obtain the required medical and financial data.

## BWMC

BWMC states that successful follow-up will be predicated on effective policies and procedures for patient recruitment, in which the physician and medical data coordinator will clearly inform and educate patients about the study, the importance of follow-up data, and the consenting process and documentation. Because BWMC's service area includes large numbers of people who speak Spanish or Korean as a first language, the hospital will provide consent documents in these languages and will provide translators upon request.

BWMC indicates that it will obtain the following information on study participants: primary and secondary addresses; telephone numbers; e-mail addresses; contact information for a relative or close friend who does not live at the same address; employer name and address; and the name and contact information of all physicians involved in the care of the patient. Patients will be encouraged to notify the hospital of any changes in their contact information, and will be given a card summarizing the follow-up schedule and providing the data coordinator's contact information. Patients will receive reminders about follow-up by mail and e-mail that will be sent between the third and sixth month and between the sixth and ninth month, and will include reminders to notify BWMC about changes in contact information; self-addressed stamped contact forms will be provided.

According to its application, BWMC will devote two FTEs to data collection and follow-up who will generally work Monday through Friday, although follow-up calls will be made in the evening and on weekends. The first follow-up call, at six weeks post-procedure, will be made to the patient's primary telephone number during the regular business day. If unanswered, a message will be left. If there is no response within two days, the number will be called again during the evening. Should the patient not respond within two days, a call will be placed to the same number on a weekend. In the absence of a response, the process will be repeated for each contact number provided by the patient. If BWMC does not hear from the patient, the patient-designated alternative contacts will be called during regular business hours, in the evening, and on weekends, as needed. If these attempts are unsuccessful, a letter will be sent to all known addresses requesting that the patient contact the data coordinator. The patient's primary care provider will be contacted and asked to relay the request for contact to the patient and/or provide the most recent patient contact information.

At each follow-up, the patient will be asked to provide updated contact information, best day and time for future follow-up, and to verify the contact information for a person not living at the same address. Patients will be asked to identify all locations (e.g., hospitals or doctor's offices) where they received care since their most recent C-PORT E study-related encounter with



BWMC. As an added incentive for each of the four follow-up times, patients who respond promptly (not defined) will receive a \$10.00 gift card. Those who respond promptly on all four occasions will receive an additional gift card worth \$15.00. Patients will be informed about the incentive program at the time of recruitment. Patients will be considered lost to follow-up only if all of the described mechanisms and processes fail to establish patient contact, and alternative contact procedures are unsuccessful.

## HCH

HCH indicates that its follow-up plan was developed in collaboration with Somerset Medical Center, a New Jersey hospital that is participating in the C-PORT E study. HCH states that it will hire an incremental 1.5 FTEs to perform follow-up. In addition, at least two staff members will be trained to obtain follow-up data, and at least two hospital employees will be trained to collect billing information.

According to the hospital, the HCH follow-up plan begins with patient recruitment and the acquisition of information to be entered into the hospital's C-PORT Follow-up database. The Clinical Research Nurse (CRN) will interview the patient and family, review the patient's role and responsibilities with regard to follow-up, and explain the importance of follow-up. The CRN will initiate and cultivate a relationship with the patient and family, and encourage them to view study nurses as "ambassadors" in the coronary care units. During the interview, the CRN will review the follow-up schedule and details, and obtain patient contact information and information about alternative contacts, including preferred time of day and week, telephone numbers, postal and e-mail addresses, family contacts, and primary care and consultant physicians. Prior to discharge or transfer to another facility, the CRN will provide the patient/family with a letter detailing the follow-up process and confirming the contact information. The CRN also will solicit a Release of Medical Information to assure that HCH will be able to obtain information from other health care providers.

HCH notes that it will place a courtesy post-discharge call to the patient/family to ensure satisfaction, address concerns, review the follow-up process, confirm contact information, and to remind patients to contact the CRN in the event they have questions or concerns. Birthday and holiday cards will be sent to patients, as appropriate, as part of the relationship building process. The CRN will monitor the Hospital Information System for the scheduling of study participants for other hospital visits and will use those opportunities for additional patient contact, as well as to identify additional hospital visits that need to be documented as part of the study protocol.

According to the HCH plan, the patient will receive a reminder letter and a confirmatory telephone call from the hospital two weeks before the expected date of follow-up. Telephone follow-up will occur Monday through Friday during daytime and evening hours, or on weekends depending upon patient preference. In the event of failure to establish follow-up contact with a patient, HCH will call the patient on various days, at various times, and using all telephone numbers provided by the patient. In addition, postal and e-mail contacts will be attempted, as will contact with designated family members or others. The follow-up form will be mailed to the patient for self-completion and return to the CRN. HCH also will contact the patient's cardiologist and other physicians to enlist their assistance in encouraging the patient to respond

and/or to obtain updated patient contact information. HCH will monitor the Social Security Death Index database and the Kaiser Permanente database for information about office visits and physician notes (if applicable). The plan provides for a patient residence visit if all other contact attempts are unsuccessful. A patient will be considered lost to follow-up only if all contact options have been exhausted and the requisite data not obtained.

### JHBMC

JHBMC reports that it will add two additional FTE nurses to the study team who will be dedicated to collecting and managing follow-up data. These nurses will be associated with the JHBMC General Clinical Research Center, an in-hospital entity that trains nurses to audit charts and complete case study forms. The two nurses as well as other study staff will be scheduled so that follow-up coverage is available seven days a week during the day and evening shifts. One FTE billing coordinator will be responsible for collecting and entering financial data both from the applicant hospital and other facilities involved in the care of study enrollees throughout the follow-up period.

The hospital indicates that during the patient recruitment process, JHBMC staff will explain the study and the importance of follow-up. The hospital will enroll only patients who agree to provide follow-up information as required under the C-PORT E study protocol, and will exclude patients without a fixed address or a telephone. JHBMC will obtain: the patient's social security number, addresses and telephone numbers; day(s) and time(s) of day that are most convenient for obtaining follow-up information; the name and contact information for another person not living at the same address; and, the name, address, e-mail address, and telephone and facsimile numbers for the patient's primary care physician and cardiologist. Study staff will work with the patient to pre-determine how the 9-month follow-up ECG will be obtained.

JHBMC states that at the designated follow-up times, staff will attempt telephone contact at least three times at three different time intervals, first at the agreed-upon time; second, on a weekday between 0900 and 1800; third, during the same interval on Saturday or Sunday. The next contact will be the patient's cardiologist and then the patient's primary care physician. Further attempts to contact the patient will be based on any new information provided by the cardiologist and/or primary physician.

According to the hospital, if patient contact is not established, it will query the Social Security Death Index database, review local obituary notices, review patient registry databases at the hospital and at Johns Hopkins Hospital for recent readmissions, visits, and/or testing, and send a letter to the patient's address of record requesting contact with the study coordinator. Information obtained from any of these sources will be entered into the patient record and will lead to new attempts to contact the patient, as appropriate. If JHBMC is unable to establish patient contact through any of these processes, the patient will be considered lost to follow-up.

### SGAH

SGAH states that, because of the magnitude of the follow-up component of the study, the SGAH Cardiac and Vascular Research Department will provide a minimum of 1.5 FTE nurses to

the project. These positions are independent of the CCL staff who will care for patients enrolled in the C-PORT E study. In addition, the hospital's director of finance has identified two staff members who will facilitate the collection of the requisite billing data.

SGAH indicates that a cardiologist and a member of the study team will approach each eligible patient to describe the study, including the importance of timely collection of follow-up data. The patient will be advised that follow-up will continue through nine months post-procedure, and include both medical and billing information from SGAH, the designated tertiary center, and any other health care provider and/or facility that cares for the patient for any reason during the follow-up period. Signed consent will be sought only if the patient has a clear understanding of the study.

According to SGAH, if consent is obtained, the patient will complete three forms. The Authorization to Release Information Form allows the hospital to obtain the patient's medical records from other hospitals. The Patient Contact Information Form records: the patient's preferred means of, and time for contact; the patient's address and telephone numbers; the names and contact information for two relatives or friends not residing in the same household; and, contact information for the patient's primary care physician. The Release of Information Consent allows the hospital to release information about the patient, identifies someone with whom the hospital may leave information if the patient is unavailable, and permits the hospital to leave messages on the patient's answering machine (if applicable). Following the npPCI procedure, the follow-up schedule will be reviewed with the patient prior to discharge.

Based on the hospital's reported experience, SGAH study staff plans to initially attempt to contact study participants by telephone during routine business hours; calls will be placed to their home and cellular telephones and to their place of employment. If these attempts are unsuccessful, the patient will be called during the weekend; SGAH notes that the hospital has had considerable success in contacting patients on Sunday evenings. In some cases, follow-up data may be obtained when the patient returns to the hospital for post-procedure visits. Study staff also will work with Cardiac Rehabilitation staff to determine if patients enrolled in the study are participating in those programs because follow-up can often be obtained when a patient is in the hospital for rehabilitation services.

If patient follow-up contact cannot be established through these processes, SGAH will contact the patient's primary care provider or cardiologist to determine if either has had recent contact with the patient. If not, study staff will contact the previously designated family member(s) or friend(s).

SGAH indicates that it maintains a research database through the admitting and billing department in which C-PORT E study participants will be listed. If a patient is admitted to the hospital while the study is in progress, the study's research manager will be automatically notified. SGAH notes that patients in the hospital's service area who are not treated at the hospital typically are treated at Washington Adventist Hospital (WAH). WAH is SGAH's tertiary care partner, and the two have a long history of cooperation. Study staff will work with the WAH medical records group to determine if the latter has any follow-up or other information

germane to study participants who have not responded to the contact attempts. If after repeated attempts none of these mechanisms results in contact, the patient is deemed lost to follow-up.

### SMHC

SMHC states that it will dedicate 1.5 FTE staff to data collection and follow-up. A data coordinator will meet with study participants, when possible, to explain the follow-up process. This personal contact is considered to be a key to facilitating subsequent follow-up. As a first step in the SMHC patient follow-up program, the hospital will require all physician investigators and data coordinators to complete a National Institutes of Health online course in the protection of human subjects. SMHC indicates that this training will guide all interactions with prospective study participants. The hospital expects to add one new staff member to the hospital's Finance Department to be responsible for collecting financial data regarding study enrollees throughout the follow-up period.

The hospital notes that it will develop a checklist of information that the study staff will collect from patients in conjunction with the consenting process; these include primary and backup patient contact information, alternative telephone numbers, and contact information for persons inside and outside of the patient's household. At the appropriate follow-up times, attempts to contact the patient will be made Monday through Friday, with call times extending into the evening, if necessary.

### SAH

SAH reports that it is currently recruiting one FTE Cardiovascular Data Coordinator (CDC) to oversee and manage the hospital's pPCI program. The CDC also will be responsible for data collection and management of the npPCI program and will lead a team of five FTE CCL nurses and the CCL secretary (one FTE), who currently collect and enter clinical data. The CDC will be on-site Monday through Friday and pager accessible around the clock. On Saturdays and Sundays, an on-site nurse will cover the CCL from 0700 until 1900, and will perform some of the CDC's functions, e.g., patient randomization and follow-up data collection. A billing coordinator will be hired to gather and enter all financial information relevant to study enrollees, and analysts from the SAH Clinical Research Center will be trained to assist in these activities.

Prior to randomization, the CDC or weekend nurse will gather and verify the patient's demographic data, including: name, birth date, and address; day, evening, and cellular telephone numbers; social security number; next of kin; and, contact information for primary care provider and cardiologist. Prospective study participants will not be randomized if more than one of these parameters is in question.

According to the hospital, SAH's consent form currently includes a statement allowing the release of information from a hospital to which the patient may be transferred. This statement will be modified to include the release of data from the offices of the interventionalist, cardiologist, and primary care physician, and from a reliable family member. These changes are expected to enhance the hospital's ability to obtain follow-up data.

SAH indicates that on post-discharge days 35, 170, and 260, the CDC will attempt to telephone the patient using the best day, time, and means information provided by the patient. If the patient is successfully contacted, the requisite follow-up information will be obtained, and preferred contact information will be established for the next scheduled follow-up period. If this attempted contact is not successful, calls will be placed on different days and at different times of day through days 40, 178, and 268 post-discharge. If unsuccessful, the patient will be sent a letter (days 42, 180, and 270) requesting the necessary follow-up data in the form of a checklist that the patient can complete and return in a self-addressed, stamped envelope. At the same time, the CDC will contact the patient's primary care physician, cardiologist, and/or designated family member for assistance in contacting the patient. A patient will be considered lost to follow-up if there is no response by day 56, 194, or 284.

### Analysis and Findings

Commission regulations require that a hospital obtain follow-up information for 98% of enrolled patients. The C-PORT E study protocol requires that follow-up be obtained for 100% of participants and provides that failure to do so may result in a hospital's suspension or termination from the study. Table 12 summarizes the applicant-provided information regarding the processes and practices each will use to obtain follow-up information.

**Table 12. Applicant Hospitals' Plans to Obtain Follow-up Data on Study Participants.\***

|                            | AAMC            | BWMC           | HCH               | JHBMC           | SGAH              | SMHC           | SAH             |
|----------------------------|-----------------|----------------|-------------------|-----------------|-------------------|----------------|-----------------|
| Dedicated Follow-up Staff  |                 |                |                   |                 |                   |                |                 |
| Medical Follow-up          | 2+ <sup>A</sup> | 2 <sup>B</sup> | 3.5+ <sup>C</sup> | 2+ <sup>D</sup> | 1.5+ <sup>E</sup> | 1.5            | 7 <sup>F</sup>  |
| Financial Follow-up        | 2               | 2 <sup>B</sup> | 2                 | 1+              | 2                 | 1 <sup>A</sup> | 1+ <sup>A</sup> |
| Follow-up Processes        |                 |                |                   |                 |                   |                |                 |
| Telephone                  | Yes             | Yes            | Yes               | Yes             | Yes               | Yes            | Yes             |
| Mail                       | Yes             | Yes            | Yes               | -               | -                 | -              | Yes             |
| E-mail                     | -               | Yes            | Yes               | -               | -                 | -              | -               |
| Alternative Contacts       | Yes             | Yes            | Yes               | Yes             | Yes               | Yes            | Yes             |
| Provider Contacts          | -               | Yes            | Yes               | Yes             | Yes               | -              | Yes             |
| Residence Visit            | -               | -              | Yes               | -               | -                 | -              | -               |
| Patient Incentives         | -               | Yes            | -                 | -               | -                 | -              | -               |
| Follow-up Incentives       | -               | Yes            | -                 | -               | -                 | -              | -               |
| Lost to Follow-up Criteria | No              | Yes            | Yes               | Yes             | Yes               | -              | Yes             |

\* A Dash (-) Indicates that the Process or Practice was not Addressed in the Hospital's Application; a Plus (+) Indicates that Other Staff Will Participate in Obtaining Follow-up.

<sup>A</sup> Includes one new position

<sup>B</sup> May include new positions

<sup>C</sup> Includes 1.5 new positions

<sup>D</sup> Two nurses from the JHBMC General Clinical Research Center responsible for follow-up with assistance by other study staff

<sup>E</sup> 1.5 nurses from the SGAH Cardiac and Vascular Research Department responsible for follow-up with assistance by other study staff

<sup>F</sup> Includes one new position (Cardiovascular Data Coordinator), five CCL nurses, one CCL secretary

Several applicants indicate an intention to hire staff dedicated to obtaining follow-up and engaging in other aspects of data acquisition and management for the study. In addition, all anticipate that clinical staff will participate in obtaining follow-up data, particularly as the volume of study participants increases. Consequently, the number of staff involved in medical follow-up likely will be greater than indicated in Table 12. Obtaining npPCI procedure-related billing information as well as billing information for post-procedure care for any reason is critical to the successful conclusion of the C-PORT E study. The applicants have made provisions for follow-up through new hires and/or training current staff.

All follow-up efforts will rely on establishing telephone contact with the patient and involve pre-establishing preferred contact dates, times, and numbers. Contact protocols typically provide for using alternative numbers, days and times, seeking updated numbers or other information from pre-identified family members, friends, and the patient's health care providers. AAMC, BWMC, HCH, and SAH will, if necessary, attempt to contact unresponsive patients by mail, and BWMC and HCH expect to communicate with patients by e-mail. HCH includes residence visit as a means of obtaining follow-up. All but AAMC and SMHC identify criteria for declaring a patient lost to follow-up.

AAMC and SGAH note the importance of establishing liaisons with medical and billing staff at other hospitals and providers to facilitate the collection of follow-up data. BWMC will provide consent forms in other languages, e.g., Spanish and Korean, and will arrange for translators to facilitate dialogue with prospective study participants. BWMC also plans to offer patient incentives to support the follow-up process. Patients with whom follow-up contact is timely established will receive a gift card at each follow-up interval; those who respond promptly at all follow-up times will receive an additional gift card.

With the exception of SMHC, the applicants have provided considerable detail regarding the processes and practices to be used to obtain the requisite follow-up information. The cardiology groups at each applicant hospital have experience obtaining follow-up data from pPCI patients, and these processes and practices have been adapted in planning for the acquisition of npPCI patient follow-up.

The pPCI patient follow-up rate at each hospital (see Table 22) may be instructive in terms of assessing its ability to achieve a follow-up rate of 98%. Based on all patients receiving pPCI at each hospital during calendar years 2006 and 2007, those with the greatest follow-up rates were BWMC (99.3%), SGAH (96.7%), and SAH (95.7%). These hospitals are considered most likely to meet the Commission's 98% follow-up rate requirement. JHBMC (92.5%) and SMHC (91.5%) are considered to be likely to meet the requirement because this level of successful follow-up among unselected patients receiving emergent care bodes well for obtaining follow-up from patients who volunteer to participate in a study of an elective procedure. Follow-up rates at AAMC (83.5%) and HCH (75.3%) improved between 2006 and 2007, but remained below those of the other applicants.

Each applicant is committed to achieving a 98% follow-up rate among patients enrolled in the C-PORT E study and is consistent with this criterion.

## B. ADDITIONAL FACTORS CONSIDERED

**COMAR 10.24.05.04.A(3):** *In determining whether to grant a waiver application, the Commission shall consider appropriate factors, including:*

- (a) An applicant's potential to improve the geographic distribution of cardiovascular services;*

### Responses of Applicants

#### AAMC

AAMC states that it serves residents of Anne Arundel and parts of Calvert, Prince George's (Bowie), and Queen Anne's (Kent Island) Counties and that there currently is no provider of npPCI services in any of those areas. AAMC says that patients from the hospital's primary and secondary markets who require npPCI travel, primarily, to the Washington Hospital Center, which is 27.9 miles away. The hospital notes that it is closer to Kent Island than is Peninsula Regional Medical Center, the only open heart surgical hospital on the Eastern Shore. AAMC states that it is more accessible to some Calvert County residents than are surgical hospitals in the vicinity of Baltimore or Washington, DC and that it is more accessible to some Calvert County residents than most of the other npPCI research waiver applicants.

AAMC reports that during 2007, it commissioned a survey of residents in ZIP codes constituting the hospital's self-defined primary, secondary, and tertiary service areas and of residents in parts of Prince George's and Queen Anne's Counties. Among other findings, AAMC noted that 34% of the 705 persons surveyed expressed a preference for AAMC relative to nine other hospitals in the region.

AAMC indicates that it offers an array of cardiovascular services including: cardiology; vascular surgery; cardiac catheterization; interventional radiology; electrophysiology; CT angiography; cardiac MRI; imaging services at five sites; and vascular screening at three sites. AAMC is an accredited Chest Pain Center, a Joint Commission-certified Advanced Stroke Center and a Maryland Institute of Emergency Medical Services Systems (MIEMSS) designated Stroke Center, and has progressive care and critical care units. AAMC's relevant certifications and accreditations are indicated in Table 17. The hospital also operates a cardiopulmonary rehabilitation program. AAMC offers free vascular screening in Annapolis and Bowie, and will offer the service in Queen Anne's County at its Kent Island outpatient medical facility, which opened in April 2008; similar services are being planned for Odenton (Anne Arundel County) and Calvert County.

AAMC states that its receipt of an npPCI waiver would facilitate increased access to all hospital-offered cardiovascular services by reducing or eliminating the need for patients to travel to the Baltimore or Washington, DC areas for care. The hospital provided letters from cardiac physicians in the area indicating a willingness to refer npPCI patients to the hospital. AAMC states that the addition of npPCI would complement existing services and enhance access to follow-up care.

## BWMC

BWMC states that it serves Anne Arundel and parts of Baltimore and Howard Counties and parts of Baltimore City. Cardiovascular services comprised 20% of the hospital's inpatient services through December 31, 2007, making it the largest inpatient service at the hospital. During FY 2007, BWMC had 3,651 total cardiovascular discharges and 1,409 chest pain observation patients who stayed at the hospital for fewer than 23 hours. During CY 2006, 841 people from the ten ZIP codes that account for 80% of the hospital's inpatient discharges received PCI services at any of 14 other Maryland hospitals; 563 people from these ZIP codes received PCI services at other Maryland hospitals during the first three quarters of CY 2007. During CY 2004, 261 Anne Arundel County residents received PCI services at hospitals in Washington, DC.

BWMC notes that the pending expansion of Fort Meade will likely result in a 10,000 to 15,000 person increase in population that is projected to be concentrated in western Anne Arundel and eastern Howard Counties, in close proximity to BWMC. The hospital is scheduled to open a new medical office building in western Anne Arundel County in the spring of 2009. Arundel Heart Associates, one of BWMC's major cardiology groups, recently opened a satellite practice in western Anne Arundel County in anticipation of the expected growth.

BWMC is located among cardiac surgery hospitals in and around both Baltimore City and Washington, DC; six surgical hospitals are between 14.1 and 34.3 miles away. BWMC states that its location provides easy access for patients from Anne Arundel and Howard Counties, and from the mid-region of the Eastern Shore. Like BWMC, the three hospitals serving the mid-shore region (Memorial Hospital at Easton, Dorchester General, and Chester River Hospital) are or will soon be part of the University of Maryland Medical System. Cardiology providers at these facilities already have a strong referral relationship with the University of Maryland Medical Center (UMMC), which maintains a helicopter at Easton Memorial that is used to transport cardiac patients to UMMC.

According to BWMC, its cardiovascular service portfolio includes stress testing, transesophageal echocardiograms, cardioversion, electrophysiology studies, pacemaker / automatic implanted cardioverter defibrillator insertion, intra-aortic balloon pump insertion, cardiac catheterization, and primary angioplasty. BWMC is a MIEMSS-designated Stroke Center; its other relevant accreditations and certifications are presented in Table 17. The hospital has a 12-bed coronary care unit, a dedicated vascular center for outpatient consultation that includes diagnostic ultrasound, and a cardiopulmonary rehabilitation center. BWMC maintains a dedicated endovascular suite that is separate from the CCL and is where minimally invasive treatments are provided to patients with peripheral vascular disease, renal artery disease, or other conditions, or patients who require carotid stenting.

BWMC provided copies of letters from physicians who currently perform npPCI at UMMC agreeing to assign npPCI cases to BWMC if the hospital receives a research waiver. The hospital states that this will reduce the need for patients in the BWMC service area to travel to more distant surgical hospitals. BWMC anticipates that enhanced access to npPCI services



will result in increased access to other cardiovascular services because patients will be able to obtain the full suite of services at BWMC, while at the same time increasing access to tertiary services at UMMC.

### HCH

HCH reports serving Montgomery and Prince George's Counties. During FY 2007, 6,235 patients received cardiac care at the hospital as emergency, inpatient, or observational patients. The majority of these patients reside in Montgomery County, although 19% are from Prince George's County.

HCH notes that Montgomery County has 1,779 people per square mile and Prince George's has 1,659 per square mile. The combined population of these counties during CY 2006 was nearly 1.8 million, and the population is projected to increase by almost 95,000 (5.3%) by 2011. During this period, the population of seniors (the source of most cardiac patients) in these two counties is expected to increase from 185,563 to 225,136 (21.3%). The hospital identifies a core market area from which it draws 44% of all patients. This core area has a population density of 2,723 per square mile. HCH states that patients from its core market area as well as other parts of the two counties would have greater access to npPCI if HCH participated in the C-PORT study.

HCH states that it provides care to large numbers of patients who are affiliated with Kaiser Permanente and are currently referred to hospitals in Washington, DC for npPCI. The hospital states that patients not affiliated with Kaiser also travel to Washington to receive npPCI services. For example, in 2006, 869 patients from the hospital-defined service area had a PCI in Washington. Receipt of a research waiver by HCH would provide people in Montgomery and Prince George's Counties with an additional choice in selecting an npPCI provider, which would enhance geographic access to this service. The hospital also asserts that the "fragility" of Prince George's County's only cardiac surgery hospital, Prince George's Hospital Center, provides HCH with an opportunity to improve access to services for people in Prince George's County.

The hospital is a Joint Commission-certified Advanced Stroke Center and a MIEMSS-designated Stroke Center. HCH's other relevant certifications and accreditations are indicated in Table 17.

### JHBMC

JHBMC notes that it serves communities in southeast Baltimore City and adjacent areas in Baltimore County. The hospital states that its proximity to I-95 and I-895 provides easy access for patients from northern Baltimore County and Harford County.

JHBMC states that its current pPCI program will be enhanced by the addition of npPCI because the total number of PCI procedures performed by JHBMC interventionalists will increase and there is a well-established relationship between institutional and physician volume, and outcome success. It notes that, currently, patients with suspected coronary artery disease (CAD) must choose between (1) having a diagnostic cardiac catheterization at JHBMC and

going elsewhere for npPCI, and (2) going elsewhere for both catheterization and npPCI. JHBMC states that both scenarios require travel outside of the patient's immediate community and engaging the services of unfamiliar physicians, resulting in possible treatment delay and increased costs. In addition, some patients may be unwilling to transfer elsewhere.

According to JHBMC, receipt of an npPCI research waiver would eliminate the need for patients to make such difficult choices and diminish the inherent medical, emotional, and financial costs associated with such decisions. Under the research waiver program, JHBMC patients would be able to receive needed care from their own physicians in their own community. According to the hospital, from 2002 through 2006, an average of 260 JHBMC patients received a diagnostic cardiac catheterization and/or npPCI each year at another hospital. Such patients would realize improved geographic access to services if the hospital received a research waiver.

The hospital is a Joint Commission-certified Advanced Stroke Center and a MIEMSS-designated Stroke Center. JHBMC's other relevant certifications and accreditations are indicated in Table 17.

### SGAH

SGAH indicates that it serves communities located along the I-270 corridor in Montgomery and Frederick Counties, an area undergoing rapid population growth and development. The hospital defined service area, which includes Germantown, Gaithersburg, Rockville, and parts of Silver Spring, was estimated to have 597,776 residents in 2007 and is projected to increase by 6.5% to 636,294 in 2012. Over the same period, the Montgomery County population is expected to increase by 4.2% and the State population by 4.3%. The hospital states that people 45 and older (those most likely to receive npPCI) constituted 35.3% of the Montgomery County population in 2000, 39.8% in 2007, and are projected to comprise 42.9% of the population in 2012. This suggests that the number of potential npPCI patients in the county is rapidly increasing. The proportion of people in this age group in Montgomery County is greater than the proportion statewide during each of the three respective periods, i.e., 34.4%, 38.2%, and 41.3%.

Through the twelve months ending September 30, 2007, SGAH reported that it recorded 75,631 emergency department (ED) visits, and the hospital's Germantown Emergency Medical Center had 25,364 ED visits. These ED visits, totaling 100,995, contribute to the success of the hospital's current pPCI program, which is characterized by high volumes, notable door-to-balloon times, a high degree of technical success, and good patient follow-up. During calendar year 2007, 10 patients were transferred from the Germantown center to SGAH for pPCI; all were discharged home in stable condition.

In addition to providing pPCI, SGAH indicates that it offers comprehensive cardiac care to the community. The hospital is accredited as a Chest Pain Center (Cycle 1), and, according to the hospital, is applying for Cycle II accreditation and PCI designation by the Society of Chest Pain Centers. Under its current accreditation, any patient arriving at either ED has an average EKG wait time of 8 minutes. For those patients without myocardial infarction, the average wait time for a provocative stress test is 6.2 hours, seven days a week. Both the nuclear medicine and

cardiology departments are routinely staffed on weekends and offer all types of diagnostic stress testing and echocardiography. SGAH also is accredited as a Cardiac Rehabilitation Center. This disease prevention and management program has served the community for 15 years, and will be available to all npPCI patients. In 2007, the center staff had over 24,000 patient encounters.

SGAH states that, because the two closest open heart surgical hospitals, Suburban Hospital and Washington Adventist, are 10.4 and 18.1 miles away, respectively, establishing an npPCI service at SGAH would improve geographic access for patients in the hospital's service area. The experience and success of the hospital's pPCI program and the volume of patients visiting the hospital's EDs annually demonstrate SGAH's commitment to patient care.

The hospital is a MIEMSS-designated Stroke Center. SGAH's other relevant certifications and accreditations are indicated in Table 17.

### SMHC

SMHC, located in southern Prince George's County, states that it serves residents of that county, and parts of Anne Arundel, Charles, and St. Mary's Counties, and Washington, DC. The hospital says that patients from these areas who require open heart surgery or npPCI currently must travel to hospitals in and around Washington, DC or Baltimore City. There are three cardiac surgery hospitals in Washington, DC, two in Montgomery County, and one in Prince George's County. It notes that it is the only applicant from Prince George's County who has applied for an npPCI waiver and states that it is the best positioned hospital to care for patients in the southern portion of the Metropolitan Washington planning region.

SMHC suggests that improved geographic access might be measured by assessing the number of people who are closer to each applicant hospital than to any existing cardiac surgery hospital. SMHC assigned each ZIP Code in the five county Metropolitan Washington region to the closest of the six existing open heart surgery/npPCI hospitals and three npPCI research waiver applicant hospitals based on the distance to the hospital from the center of each ZIP Code. ZIP Codes assigned to each hospital are defined as the hospital's Access Improvement ZIP Codes. On the basis of this analysis, SMHC concluded that HCH has 17 Access Improvement ZIP Codes, SGAH has 25, and SMHC has 66.

SMHC states that, based on 2007 population data, the total population over age 14 in its Access Improvement ZIP Codes was 427,820. The corresponding totals for SGAH and HCH were 391,529 and 312,219, respectively. SMHC says that the total population projections for 2012 follow the same pattern: SMHC (472,184); SGAH (421,708); and HCH (326,270). SMHC concludes that its receipt of an npPCI research waiver would increase geographic access to those services for more people than would be achieved by granting a waiver to either HCH or SGAH.

The hospital is a MIEMSS-designated Stroke Center, and is an accredited Chest Pain Center (Cycle I). SMHC states that it is applying for Cycle II accreditation with the Society of Chest Pain Centers. The hospital's other relevant certifications and accreditations are indicated in Table 17.

## SAH

According to the hospital, SAH serves southwest Baltimore City, southwest Baltimore County, northern Howard County, and is the designated primary provider for patients from BWI Thurgood Marshall Airport. The hospital is easily accessible from communities in the metropolitan Baltimore area and from the I-95 Corridor, and is close to three stations of the MARC system that provides commuter rail service between Baltimore and Washington, DC.

SAH describes operating a 7-bed chest pain emergency department that has Cycle II accreditation with PCI designation from the Society of Chest Pain Centers. The hospital has Advanced Stroke Center accreditation from the Joint Commission, and is a MIEMSS-designated Stroke Center. Its other relevant accreditation and certifications are indicated in Table 17. Other facilities include a newly renovated multidisciplinary cardiovascular suite with two CCLs, two interventional radiology laboratories, an 8-bed catheterization preparation and recovery area, and a procedure room. The hospital notes that it performs more than 950 diagnostic cardiac catheterizations annually, and states that it is a nationally recognized leader relative to outcomes and mortality rates for cardiac care. SAH sponsors a Heart Aware Risk Assessment Profile program in conjunction with St. Joseph Medical Center.

Based on its analysis of statewide emergency department visit data for FY 2007, SAH had 3,932 ED visits with principal diagnoses of cardiovascular problems (ICD-9 diagnostic codes 390-459). SAH states that about 70% of all cardiovascular-related ED visits result in hospital admission. The hospital states that, during the 12-month period ending September 30, 2007, there were a total of 12,674 cardiovascular-related ED visits by people residing in the sections of Anne Arundel, Baltimore, and Howard Counties and Baltimore City that comprise the SAH-defined service area. According to SAH, among people living in the hospital-defined service area there were nearly 2,150 visits for ischemic heart disease resulting in 1,715 PCI procedures; 1,265 were performed on an emergent or urgent basis. Almost 47% of the PCI patients (805) required transfer to another hospital for the intervention.

SAH states its belief that receipt of an npPCI research waiver will increase access for thousands of patients from the southwest Baltimore metropolitan area who require emergent services for cardiovascular disease. The hospital says that the addition of npPCI services will provide a gateway to its existing cardiovascular facilities, and the risk assessment, diagnostic, therapeutic, and management services that already are available at the hospital.

## Analysis and Findings

In considering geographic access, the Commission recognizes that residents of the State's metropolitan service areas generally have good access to npPCI, an elective procedure provided by hospitals with on-site cardiac surgery. Although most applicants view improving geographic access in terms of reducing travel distance and time for patients referred to more distant hospitals for npPCI, the Commission views this from several different perspectives.

The Commission notes that Maryland has designated the following counties as rural: Allegany; Calvert; Caroline; Carroll; Cecil; Charles; Dorchester; Frederick; Garrett; Harford; Kent; Queen Anne's; Somerset; St. Mary's; Talbot; Washington; Wicomico; and Worcester Counties. Those jurisdictions are mandated by State law to have representatives on the Rural Maryland Council. For the purpose of determining eligibility for funding, the federal Office of Rural Health Policy (ORHP) also has designated Allegany, Caroline, Dorchester, Garrett, Kent, Somerset (5 out of 7 census tracts), St. Mary's, Talbot, and Worcester Counties as rural.<sup>15</sup> Thus, a hospital located in close proximity to these counties that is awarded an npPCI research may provide improved access for some rural Marylanders.

Another Commission perspective on improving geographic access is the ongoing concern that clinical studies accurately reflect the racial and ethnic diversity of the State's population. Although this will be examined more closely in the next section, there is a substantial body of scientific and policy literature documenting the under-representation of women, minorities, and other population groups in large numbers of clinical studies.<sup>16</sup> Because the results of the C-PORT E study may be germane to future considerations by the Commission regarding the statewide distribution of PCI services, this is an important aspect of the Commission's oversight of the study.

Map 1 shows the distribution of acute care hospitals in the Metropolitan Baltimore and Metropolitan Washington Regional Service Areas, noting both hospitals with on-site cardiac surgery and those that provide pPCI under COMAR 10.24.17. The distances between each applicant and the nearest OHS hospital and applicant, and the number of OHS and applicant hospitals that are within 5 miles and 5.1 to 10 miles from each applicant are indicated in Table 13. The distances between all applicants and all OHS hospitals are reported in Table 14. Under the C-PORT E study protocol and Commission regulations, npPCI procedures are elective, not emergent or urgent procedures as suggested by SAH. For this reason, the information is presented as straight line distance. Driving times between these hospitals during non-rush hour and rush hour conditions are indicated in Table 15 and Table 16, respectively.

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<sup>15</sup> State Office of Rural Health, Department of Health and Mental Hygiene, Maryland Rural Health Plan, June 2007

<sup>16</sup> See, for example, Lee PY et al., Representation of elderly persons and women in published randomized trials of acute coronary syndromes. *J Amer Med Assoc* 2001;286:708-713; Murthy VH et al., Participation in cancer clinical trials Race-, sex-, and age-based disparities. *J Amer Med Assoc* 2004;291:2720-2726

**Table 13. Jurisdictions Served, and Nearest\* Open Heart Surgical and Applicant Hospitals to Each Applicant.**

|                                    | <b>AAMC</b> | <b>BWMC</b> | <b>HCH</b>  | <b>JHBMC</b> | <b>SGAH</b>  | <b>SMHC</b>  | <b>SAH</b>       |
|------------------------------------|-------------|-------------|-------------|--------------|--------------|--|------------------|
| <b>Counties Served<sup>A</sup></b> | AA, PG, QA  | AA, BCI     | MO, PG, HO  | BCI, BCO     | MO           | PG, CH, SM   | BCI, BCO, HO, AA |
| <b>Nearest OHS Hospital</b>        | UMMC (21.3) | UMMC (10.3) | WAH (2.9)   | JHH (2.1)    | Suburb (8.6) | PGHC <sup>B</sup> (12.5)<br>/GWU (13.8)/<br>WHC (15.4) | UMMC (2.8)       |
| <b>Number within 5 miles</b>       | 0           | 0           | 2           | 3            | 0            | 0  | 3                |
| <b>Number 5.1-10 miles away</b>    | 0           | 0           | 4           | 2            | 1            | 0  | 2                |
| <b>Nearest Applicant</b>           | BWMC (11.6) | SAH (9.6)   | SGAH (10.6) | SAH (6.3)    | HCH (10.6)   | HCH (20.1)   | JHBMC (6.3)      |
| <b>Number within 5 miles</b>       | 0           | 0           | 0           | 0            | 0            | 0  | 0                |
| <b>Number 5.1-10 miles away</b>    | 0           | 1           | 0           | 1            | 0            | 0  | 2                |

\* Distance in straight line miles

<sup>A</sup> Based on counties in which the applicant's primary and extended service areas are located. Abbreviations: AA – Anne Arundel; BCI – Baltimore City; BCO – Baltimore County; CH – Charles; HO – Howard; MO- Montgomery; PG – Prince George's; QA – Queen Anne's; and SM – St. Mary's Counties.

<sup>B</sup> Prince George's Hospital Center does not meet the annual minimum volume requirement for open heart surgical procedures; George Washington University Hospital is the next closest OHS.

**Table 14. Straight Line Distances (Miles) Between Applicant Hospitals (Blue) and Open Heart Surgical Hospitals in the Metropolitan Baltimore and Metropolitan Washington Regional Service Areas (White – Maryland; Yellow - Washington, DC), and Other Regional Service Areas (Salmon) in Maryland.**

|   |       |       |                                    |       |       |  |       |       |                                  |       |       |                          |                               |       |       |       |       |       |      |  |
|---|-------|-------|------------------------------------|-------|-------|--|-------|-------|----------------------------------|-------|-------|--------------------------|-------------------------------|-------|-------|-------|-------|-------|------|--|
| HCH   |       |       |                                    |       |       |  |       |       |                                  |       |       |                          |                               |       |       |       |       |       |      |  |
| 10.6  | SGAH  |       |                                    |       |       |  |       |       |                                  |       |       |                          |                               |       |       |       |       |       |      |  |
| 20.1  | 29.6  | SMHC  |                                    |       |       |  |       |       |                                  |       |       |                          |                               |       |       |       |       |       |      |  |
| 4.2   | 8.6   | 21.0  | Suburb                             |       |       |  |       |       |                                  |       |       |                          |                               |       |       |       |       |       |      |  |
| 2.9   | 13.4  | 17.3  | 5.9                                | WAH   |       |  |       |       |                                  |       |       |                          |                               |       |       |       |       |       |      |  |
| 8.4   | 18.9  | 12.5  | 11.0                               | 5.6   | PGHC* |  |       |       |                                  |       |       |                          |                               |       |       |       |       |       |      |  |
| 8.1   | 15.9  | 13.8  | 7.4                                | 6.4   | 7.1   | GWUH   |       |       |                                  |       |       |                          |                               |       |       |       |       |       |      |  |
| 7.2   | 16.7  | 13.0  | 8.3                                | 4.6   | 3.9   | 3.3  | HUH*  |       |                                  |       |       |                          |                               |       |       |       |       |       |      |  |
| 5.2   | 14.2  | 15.4  | 5.7                                | 3.4   | 5.8   | 3.0  | 2.5   | WHC   |                                  |       |       |                          |                               |       |       |       |       |       |      |  |
| 27.0  | 36.6  | 24.9  | 31.0                               | 25.1  | 21.4  | 28.6   | 25.3  | 27.0  | AAMC                             |       |       |                          |                               |       |       |       |       |       |      |  |
| 23.5  | 30.9  | 30.1  | 27.7                               | 22.8  | 21.7  | 28.2   | 25.1  | 25.7  | 11.6                             | BWMC  |       |                          |                               |       |       |       |       |       |      |  |
| 31.8  | 37.0  | 41.0  | 35.9                               | 31.8  | 31.7  | 37.8   | 34.9  | 35.0  | 20.6                             | 10.9  | JHBMC |                          |                               |       |       |       |       |       |      |  |
| 26.4  | 30.8  | 37.8  | 30.3                               | 26.7  | 27.4  | 32.9   | 30.2  | 30.1  | 21.0                             | 9.5   | 6.3   | SAH                      |                               |       |       |       |       |       |      |  |
| 30.7  | 35.4  | 40.8  | 34.7                               | 30.9  | 31.1  | 37.0   | 34.1  | 34.1  | 21.5                             | 11.0  | 2.1   | 4.6                      | JHH                           |       |       |       |       |       |      |  |
| 30.7  | 33.8  | 43.3  | 34.4                               | 31.4  | 32.6  | 37.7   | 35.1  | 34.8  | 26.2                             | 15.0  | 7.5   | 5.6                      | 5.5                           | Sinai |       |       |       |       |      |  |
| 34.4  | 37.4  | 46.6  | 38.1                               | 35.0  | 36.1  | 41.4   | 38.7  | 38.4  | 28.2                             | 17.4  | 7.9   | 8.8                      | 6.7                           | 3.7   | SJMC  |       |       |       |      |  |
| 31.3  | 35.2  | 42.5  | 35.1                               | 31.7  | 32.4  | 37.9   | 35.1  | 35.0  | 24.0                             | 13.2  | 4.4   | 5.0                      | 2.6                           | 3.1   | 4.3   | UMH   |       |       |      |  |
| 29.0  | 33.6  | 39.6  | 32.9                               | 29.2  | 29.7  | 35.4   | 32.5  | 32.5  | 21.3                             | 10.3  | 3.7   | 2.8                      | 1.9                           | 5.0   | 7.2   | 2.9   | UMMC  |       |      |  |
| 104.0   | 93.5  | 120.2 | 101.0                              | 106.7 | 112.0 | 106.9  | 109.0 | 106.6 | 129.5                            | 121.2 | 122.3 | 116.4                    | 120.2                         | 115.6 | 117.8 | 118.5 | 118.7 | BH    |      |  |
| 89.6  | 100.2 | 74.3  | 92.6                               | 87.0  | 81.6  | 86.8   | 84.6  | 87.0  | 66.5                             | 77.2  | 82.0  | 85.5                     | 83.8                          | 89.4  | 89.7  | 86.4  | 84.5  | 193.6 | PRMC |  |
| npPCI Research Waiver Applicants              |       |       | Open Heart Surgical Hospitals - MD |       |       | Open Heart Surgical Hospitals - DC           |       |       | npPCI Research Waiver Applicants |       |       |                          | Open Heart Surgical Hospitals |       |       |       |       |       |      |  |
| Metropolitan Washington Regional Service Area |       |       |                                    |       |       | Metropolitan Baltimore Regional Service Area |       |       |                                  |       |       | Other Areas <sup>1</sup> |                               |       |       |       |       |       |      |  |

Source: Spatial Insights, Inc., Bethesda, MD

\* Hospital does not meet the Commission's minimum volume requirement for a quality cardiac surgery program.

<sup>1</sup> Braddock Hospital (BH) is in the Western Maryland Regional Service Area; Peninsula Regional Medical Center (PRMC) is in the Eastern Shore Regional Service Area.

**Table 15. Non-Rush Hour Driving Times (Minutes) Between Applicant Hospitals (Blue) and Open Heart Surgical Hospitals in the Metropolitan Baltimore and Metropolitan Washington Regional Service Areas (White - Maryland; Yellow - Washington, DC), and Other Regional Service Areas (Salmon) in Maryland.**

|   |       |       |                                    |       |       |                                    |       |       |  |       |       |       |                               |       |       |       |       |                          |      |  |  |  |
|---|-------|-------|------------------------------------|-------|-------|------------------------------------|-------|-------|--|-------|-------|-------|-------------------------------|-------|-------|-------|-------|--------------------------|------|--|--|--|
| HCH   |       |       |                                    |       |       |                                    |       |       |  |       |       |       |                               |       |       |       |       |                          |      |  |  |  |
| 18.2  | SGAH  |       |                                    |       |       |                                    |       |       |  |       |       |       |                               |       |       |       |       |                          |      |  |  |  |
| 37.6  | 53.9  | SMHC  |                                    |       |       |                                    |       |       |  |       |       |       |                               |       |       |       |       |                          |      |  |  |  |
| 7.5   | 16.0  | 39.3  | Suburb                             |       |       |                                    |       |       |  |       |       |       |                               |       |       |       |       |                          |      |  |  |  |
| 5.5   | 23.7  | 32.2  | 10.7                               | WAH   |       |                                    |       |       |  |       |       |       |                               |       |       |       |       |                          |      |  |  |  |
| 18.3  | 36.4  | 21.9  | 23.8                               | 13.5  | PGHC* |                                    |       |       |  |       |       |       |                               |       |       |       |       |                          |      |  |  |  |
| 15.8  | 28.6  | 25.7  | 14.0                               | 14.0  | 11.8  | GWUH                               |       |       |  |       |       |       |                               |       |       |       |       |                          |      |  |  |  |
| 14.4  | 32.6  | 24.3  | 18.7                               | 8.9   | 5.4   | 6.4                                | HUH*  |       |  |       |       |       |                               |       |       |       |       |                          |      |  |  |  |
| 8.8   | 26.1  | 29.6  | 12.3                               | 6.9   | 12.1  | 7.4                                | 7.0   | WHC   |  |       |       |       |                               |       |       |       |       |                          |      |  |  |  |
| 41.5  | 59.6  | 43.1  | 48.9                               | 40.1  | 30.0  | 41.3                               | 34.9  | 39.9  | AAMC   |       |       |       |                               |       |       |       |       |                          |      |  |  |  |
| 41.0  | 59.1  | 52.5  | 48.5                               | 42.6  | 39.2  | 50.7                               | 44.3  | 48.4  | 22.8   | BWMC  |       |       |                               |       |       |       |       |                          |      |  |  |  |
| 51.6  | 67.6  | 67.7  | 59.1                               | 53.2  | 50.6  | 62.4                               | 56.0  | 59.5  | 38.9   | 18.2  | JHBMC |       |                               |       |       |       |       |                          |      |  |  |  |
| 44.2  | 60.2  | 62.0  | 51.7                               | 45.8  | 44.0  | 55.8                               | 49.4  | 52.1  | 35.8   | 15.2  | 10.8  | SAH   |                               |       |       |       |       |                          |      |  |  |  |
| 50.1  | 66.1  | 67.1  | 57.6                               | 51.7  | 49.1  | 60.9                               | 54.5  | 58.0  | 38.4   | 17.8  | 4.5   | 7.9   | JHH                           |       |       |       |       |                          |      |  |  |  |
| 55.0  | 71.0  | 72.9  | 62.5                               | 56.6  | 54.8  | 66.6                               | 60.2  | 62.9  | 44.7   | 24.1  | 14.6  | 10.9  | 10.1                          | Sinai |       |       |       |                          |      |  |  |  |
| 61.2  | 77.2  | 78.3  | 68.7                               | 62.8  | 60.2  | 72.0                               | 65.6  | 69.1  | 50.1   | 29.5  | 18.1  | 18.7  | 13.7                          | 8.6   | SJMC  |       |       |                          |      |  |  |  |
| 53.3  | 69.3  | 70.3  | 60.8                               | 54.9  | 52.3  | 64.0                               | 57.6  | 61.2  | 41.6   | 21.0  | 10.5  | 11.1  | 6.0                           | 6.0   | 8.9   | UMH   |       |                          |      |  |  |  |
| 47.4  | 63.4  | 64.4  | 54.9                               | 49.0  | 46.4  | 58.2                               | 51.8  | 55.3  | 36.2   | 15.6  | 6.2   | 5.2   | 3.3                           | 9.4   | 14.1  | 6.2   | UMMC  |                          |      |  |  |  |
| 169.3   | 153.5 | 200.9 | 167.1                              | 174.8 | 186.3 | 175.6                              | 180.9 | 177.3 | 205.0  | 185.3 | 184.0 | 174.5 | 180.0                         | 177.4 | 184.3 | 180.8 | 177.9 | BH                       |      |  |  |  |
| 141.3   | 159.4 | 142.9 | 148.7                              | 139.9 | 129.8 | 141.1                              | 134.7 | 139.7 | 99.8   | 118.9 | 133.4 | 132.9 | 135.5                         | 141.8 | 147.2 | 138.7 | 133.3 | 302.3                    | PRMC |  |  |  |
| npPCI Research Waiver Applicants              |       |       | Open Heart Surgical Hospitals - MD |       |       | Open Heart Surgical Hospitals - DC |       |       | npPCI Research Waiver Applicants             |       |       |       | Open Heart Surgical Hospitals |       |       |       |       |                          |      |  |  |  |
| Metropolitan Washington Regional Service Area |       |       |                                    |       |       |                                    |       |       | Metropolitan Baltimore Regional Service Area |       |       |       |                               |       |       |       |       | Other Areas <sup>1</sup> |      |  |  |  |

Source: Spatial Insights, Inc., Bethesda, MD

\* Hospital does not meet the Commission's minimum volume requirement for a quality cardiac surgery program.

<sup>1</sup> Braddock Hospital (BH) is in the Western Maryland Regional Service Area; Peninsula Regional Medical Center (PRMC) is in the Eastern Shore Regional Service Area



**Table 16. Rush Hour Driving Times (Minutes) Between Applicant Hospitals (Blue) and Open Heart Surgical Hospitals in the Metropolitan Baltimore and Metropolitan Washington Regional Service Areas (White - Maryland; Yellow - Washington, DC), and Other Regional Service Areas (Salmon) in Maryland.**

|   |       |       |                               |       |       |  |       |       |                                  |       |       |                          |                               |       |       |       |       |       |      |  |  |  |
|---|-------|-------|-------------------------------|-------|-------|--|-------|-------|----------------------------------|-------|-------|--------------------------|-------------------------------|-------|-------|-------|-------|-------|------|--|--|--|
| HCH   |       |       |                               |       |       |  |       |       |                                  |       |       |                          |                               |       |       |       |       |       |      |  |  |  |
| 27.4  | SGAH  |       |                               |       |       |  |       |       |                                  |       |       |                          |                               |       |       |       |       |       |      |  |  |  |
| 58.8  | 82.5  | SMHC  |                               |       |       |  |       |       |                                  |       |       |                          |                               |       |       |       |       |       |      |  |  |  |
| 12.7  | 25.0  | 62.5  | Suburb                        |       |       |  |       |       |                                  |       |       |                          |                               |       |       |       |       |       |      |  |  |  |
| 9.0   | 36.3  | 52.5  | 19.9                          | WAH   |       |  |       |       |                                  |       |       |                          |                               |       |       |       |       |       |      |  |  |  |
| 30.4  | 57.7  | 36.3  | 38.5                          | 23.0  | PGHC* |  |       |       |                                  |       |       |                          |                               |       |       |       |       |       |      |  |  |  |
| 26.4  | 42.6  | 40.8  | 22.6                          | 24.1  | 18.1  | GWUH   |       |       |                                  |       |       |                          |                               |       |       |       |       |       |      |  |  |  |
| 24.3  | 50.9  | 39.0  | 30.9                          | 15.4  | 7.6   | 10.5   | HUH*  |       |                                  |       |       |                          |                               |       |       |       |       |       |      |  |  |  |
| 16.0  | 41.5  | 47.5  | 21.7                          | 12.1  | 19.6  | 12.7   | 12.0  | WHC   |                                  |       |       |                          |                               |       |       |       |       |       |      |  |  |  |
| 60.0  | 87.3  | 64.4  | 72.6                          | 61.5  | 43.1  | 59.8   | 49.3  | 61.2  | AAMC                             |       |       |                          |                               |       |       |       |       |       |      |  |  |  |
| 61.9  | 89.3  | 79.4  | 74.6                          | 65.4  | 56.9  | 74.7   | 64.2  | 75.5  | 33.3                             | BWMC  |       |                          |                               |       |       |       |       |       |      |  |  |  |
| 73.8  | 101.1 | 100.1 | 86.4                          | 77.2  | 71.7  | 89.8   | 79.3  | 87.9  | 55.1                             | 27.1  | JHBMC |                          |                               |       |       |       |       |       |      |  |  |  |
| 63.8  | 91.2  | 92.5  | 76.5                          | 67.3  | 64.1  | 82.2   | 71.7  | 78.0  | 52.6                             | 24.6  | 16.0  | SAH                      |                               |       |       |       |       |       |      |  |  |  |
| 71.9  | 99.2  | 98.3  | 84.5                          | 75.3  | 69.9  | 88.0   | 77.5  | 86.0  | 55.9                             | 28.0  | 7.7   | 12.5                     | JHH                           |       |       |       |       |       |      |  |  |  |
| 80.9  | 108.2 | 108.1 | 93.5                          | 84.3  | 79.7  | 97.8   | 87.3  | 95.0  | 66.0                             | 38.1  | 22.6  | 20.2                     | 14.9                          | Sinai |       |       |       |       |      |  |  |  |
| 91.5  | 118.8 | 118.6 | 104.1                         | 94.9  | 90.2  | 108.3  | 97.8  | 105.6 | 76.6                             | 48.6  | 31.3  | 32.1                     | 23.9                          | 14.8  | SJMC  |       |       |       |      |  |  |  |
| 77.6  | 105.0 | 104.1 | 90.3                          | 81.1  | 75.7  | 93.8   | 83.3  | 91.7  | 61.7                             | 33.7  | 17.6  | 18.2                     | 9.9                           | 9.8   | 15.6  | UMH   |       |       |      |  |  |  |
| 68.1  | 95.5  | 94.6  | 80.8                          | 71.6  | 66.2  | 84.3   | 73.8  | 82.2  | 52.5                             | 24.6  | 10.6  | 8.8                      | 5.3                           | 14.4  | 25.0  | 10.9  | UMMC  |       |      |  |  |  |
| 226.9   | 206.4 | 270.7 | 224.6                         | 235.9 | 250.2 | 232.1  | 242.6 | 240.4 | 278.1                            | 250.5 | 249.1 | 235.4                    | 245.7                         | 240.8 | 249.8 | 247.4 | 241.4 | BH    |      |  |  |  |
| 183.7   | 211.0 | 188.1 | 196.3                         | 185.2 | 166.7 | 183.4  | 172.9 | 184.9 | 123.7                            | 157.0 | 178.8 | 176.3                    | 179.6                         | 189.7 | 200.3 | 185.4 | 176.2 | 401.8 | PRMC |  |  |  |
| npPCI Research Waiver Applicants              |       |       | Open Heart Surgical Hospitals |       |       | Open Heart Surgical Hospitals                |       |       | npPCI Research Waiver Applicants |       |       |                          | Open Heart Surgical Hospitals |       |       |       |       |       |      |  |  |  |
| Metropolitan Washington Regional Service Area |       |       |                               |       |       | Metropolitan Baltimore Regional Service Area |       |       |                                  |       |       | Other Areas <sup>1</sup> |                               |       |       |       |       |       |      |  |  |  |

Source: Spatial Insights, Inc., Bethesda, MD

\* Hospital does not meet the Commission's minimum volume requirement for a quality cardiac surgery program.

<sup>1</sup> Braddock Hospital (BH) is in the Western Maryland Regional Service Area; Peninsula Regional Medical Center (PRMC) is in the Eastern Shore Regional Service Area

Distances to the nearest OHS hospital range from 2.1 miles (JHBMC to JHH) to 21.3 miles (AAMC to UMMC). SMHC is within 14 miles of two cardiac surgery hospitals that meet the Commission's volume requirements for cardiac surgery programs; both are in Washington, DC. The nearest npPCI research waiver applicants are HCH (20.1 miles) and AAMC (24.9 miles). SMHC's receipt of a research waiver could reduce travel distance and time for npPCI patients residing in Charles, St. Mary's, and portions of Calvert Counties.

Four cardiac surgery hospitals are located between 10.3 and 15 miles from BWMC; SAH, the nearest npPCI research waiver applicant, is 9.6 miles from BWMC. HCH, JHBMC, and SAH each have at least two open heart surgery hospitals within a 5-mile radius, and at least one additional surgical hospital between 5.1 and 10 miles away. Among the applicants, JHBMC and SAH are separated by 6.3 miles, and SAH is 9.5 miles from BWMC. Similarly, HCH and SGAH are 10.6 miles apart.

Of course, factors other than distance may affect hospital utilization patterns. This is reflected in a number of applications that provided demographic data based on hospital-defined service areas. Because the applicant-defined service areas were determined using various approaches, the Commission employed the methodology described in COMAR 10.24.01.01.B.(34) to identify each applicant's primary and extended service areas.<sup>17</sup> For purposes of this review, primary service area (PSA) is defined as the ZIP Codes in which 60% of the hospital's cardiac care inpatients reside. The extended service area (ESA) is comprised of those contiguous ZIP Codes in which 85% (minus the 60% of patients residing in the PSA ZIP codes) of cardiac care inpatients reside. Calendar year 2006 inpatient data<sup>18</sup> were used to determine for each hospital the number of cardiac care patients by ZIP Code. Cardiac care inpatients were identified by Diagnosis Related Group (DRG) coding, version 22.0.<sup>19</sup>

Table 13 identifies the jurisdictions in which each applicant's primary and extended service areas are located. The PSA and ESA of each applicant are illustrated in Maps 2-8. Generally, there was limited overlap between the ZIP Code-defined service areas. Six ZIP Codes were part of the combined primary and extended service areas of both AAMC and BWMC, and one of those ZIP Codes was part of the SAH extended service area. SAH also shared one ZIP Code with BWMC and three with JHBMC. The combined PSA and ESA service areas at HCH included 12 ZIP Codes that were part of the SGAH combined service area and six other ZIP Codes that were also part of the SMHC combined service area.

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<sup>17</sup> Primary Service Area (PSA) is defined in the Acute Care Inpatient Services Chapter of the SHP, COMAR 10.24.10, as the Maryland postal ZIP Codes from which the first 60% of a hospital's patient discharges originate, where the discharges from each ZIP Code are ordered from largest to smallest. In cases where two or more ZIP Codes have the same number of discharges, the ZIP Codes are ordered from largest to smallest based on the percentage of ZIP Code discharges to the hospital during the same period. The PSA also includes those Maryland ZIP Codes physically contiguous to any of the PSA ZIP Codes that provide 50% or more of the hospital's discharges during the same period. The Extended Service Area (ESA) is comprised of those ZIP Codes providing 85% of a hospital's discharges, minus those ZIP Codes included in the PSA. In this review, the PSA and ESA look to the ZIP codes of cardiac inpatients.

<sup>18</sup> Health Services Cost Review Commission, Maryland Hospital Discharge Data Set

<sup>19</sup> DRGs 110-145, 478-479, 514-518, 525-527, 535-536

Based on cardiovascular-related discharges for 2006, AAMC is the only applicant with PSA and ESA ZIP Codes in Queen Anne's County on the Eastern Shore. The nearest OHS hospitals are in the Baltimore or Washington, DC areas, and in Salisbury. Similarly, SMHC is the only applicant with PSA and ESA ZIP Codes in Charles and St. Mary's Counties. For people in these counties, the nearest surgical hospital, Prince George's Hospital Center (PGHC), is 12.5 miles more distant than SMHC. Neither PGHC nor Howard University Hospital (13.0 miles) meets the Commission's annual minimum volume requirement for open heart surgical procedures. Two OHS hospitals in Washington, DC that meet the minimum volume requirement are between 13.8 (George Washington University Hospital) and 15.4 (Washington Hospital Center) miles from SMHC. By virtue of its location, SGAH potentially brings angioplasty services closer to upper Montgomery County.

The continuum of cardiovascular care services includes health promotion and disease prevention, primary care, secondary care, and tertiary care services. Additional information about the acute/emergency care and cardiac rehabilitation/secondary prevention components of the applicant hospitals' cardiovascular programs is provided below. The discussion focuses on the two types of accreditation/certification most directly related to coronary heart disease.

Special chest pain centers or units have been established in emergency departments to help appropriately evaluate patients with possible ACS (acute coronary syndrome) while avoiding unnecessary admissions to the hospital or the release of patients who should be admitted from the emergency department. Alternatively, a hospital may use an appropriate inpatient telemetry unit when a chest pain unit is not available. Current national guidelines state, "Patients with probable or possible ACS but whose initial 12-lead ECG and cardiac biomarker levels are normal should be observed in a facility with cardiac monitoring (e.g., chest pain unit or hospital telemetry ward), ... In patients with suspected ACS in whom ischemic heart disease is present or suspected, if the follow-up 12-lead ECG and cardiac biomarkers measurements are normal, a stress test (exercise or pharmacological) to provoke ischemia should be performed in the ED, in a chest pain unit, or on an outpatient basis in a timely fashion (within 72 h) as an alternative to inpatient admission. ... Admission to the critical care unit is recommended for those [patients] with active, ongoing ischemia/injury and hemodynamic or electrical instability. Otherwise, a telemetry step-down unit is reasonable."<sup>20</sup>

Usually a voluntary process, accreditation or certification indicates that facilities or programs have met certain standards for the delivery of services; consumers and purchasers of health care may use accreditation/certification as a proxy for quality. Under the Joint Commission's voluntary Disease-Specific Care Certification Program, which began in 2002, organizations may seek certification for clinical programs for virtually any chronic disease or condition.

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<sup>20</sup> Anderson JL, Adams CD, Antman EM, et al. ACC/AHA 2007 guidelines for the management of patients with unstable angina/non-ST-elevation myocardial infarction— executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 2002 Guidelines for the Management of Patients With Unstable Angina/Non-ST-Elevation Myocardial Infarction): developed in collaboration with the American College of Emergency Physicians, American College of Physicians, Society for Academic Emergency Medicine, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. *J Am Coll Cardiol* 2007;50:652–726.

Also voluntary, accreditation by the Society of Chest Pain Centers (SCPC) requires hospitals to document and demonstrate compliance with SCPC criteria in eight areas:

1. Integration of the emergency department with the local emergency medical system through a formal relationship;
2. Timely diagnosis and treatment of patients with symptoms of possible acute coronary syndrome (myocardial infarctions or unstable angina) to minimize delays in initiating therapy for ACS;
3. Timely assessment of patients at low risk for ACS before releasing the patients;
4. Functional design of the facility, including monitoring equipment, for evaluating patients;
5. Competencies and training of the staff providing care to patients with symptoms of ACS;
6. Organizational structure and commitment to support the chest pain center;
7. Process improvement guided by principles of continuous quality improvement; and
8. Community outreach program to educate the public.

SCPC's PCI designation began with Cycle II accreditation (every three years, SCPC revises its criteria based on research, new guidelines, and best practices). As of January 2008, 364 (9%) hospitals in the United States had SCPC-accredited chest pain centers.<sup>21</sup>

Although national guidelines for the care of patients with cardiovascular disease recommend cardiac rehabilitation programs for appropriate candidates (for example, recent myocardial infarction or acute coronary syndrome; recent PCI), it is estimated that fewer than one-third of eligible patients in the United States participate in medically supervised programs after a cardiovascular event.<sup>22</sup> As of October 2006, only 973 (37%) out of approximately 2,621 cardiac rehabilitation programs in the United States had obtained certification by the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR).<sup>23</sup> AACVPR certification is voluntary; however, the American Heart Association encourages all cardiac rehabilitation/secondary prevention programs to meet the certification standards.<sup>24</sup>

With regard to subpopulations or population groups defined by geography (urban, suburban, or rural), geographic under-representation may reduce the generalizability of the study results (i.e., whether the results can actually be applied to residents and hospitals without cardiac surgery on-site in these areas). See discussion of access to PCI services for minorities and medically underserved populations.

Each applicant provided information describing the cardiovascular services offered by the hospital in the context that receipt of an npPCI research waiver would improve the geographic distribution of the full suite of services. The described portfolio of services available at each varied, but were largely overlapping. As a gauge of an applicant's commitment to cardiac care,

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<sup>21</sup> Ross MA, Amsterdam E, Peacock WF, et al. Chest pain center accreditation is associated with better performance of Centers for Medicare and Medicaid Services core measures for acute myocardial infarction. *Am J Cardiol* 2008;102:120-124.

<sup>22</sup> Wenger NK. Current status of cardiac rehabilitation. *J Am Coll Cardiol* 2008;51:1619-1631.

<sup>23</sup> Thomas RJ, King M, Lui K, et al. AACVPR/ACC/AHA 2007 performance measures on cardiac rehabilitation for referral to and delivery of cardiac rehabilitation/secondary prevention services. *J Am Coll Cardiol* 2007;50:1400-33.

<sup>24</sup> Balady GJ, Williams MA, Ades PA, et al. Core Components of Cardiac Rehabilitation/Secondary Prevention Programs: 2007 Update: AHA/AACVPR Scientific Statement. *Circulation* 2007;115:2675-2682.

the Commission reviewed the certification/accreditation of various cardiac services at each hospital. Certification/accreditation information was determined from information provided on the websites of the relevant professional organizations. Each hospital reviewed this information and provided additional information documenting any changes in certification/accreditation status. This information is presented in Table 17.

In summary, as measured by distance to an existing OHS program, the applicants best situated to improve the geographic distribution of cardiovascular services are AAMC and SMHC. Some improvement in the geographic distribution of cardiovascular services would be realized with the location of npPCI services at BWMC and SGAH. The remaining applicants (HCH, JHBMC, and SAH) are located in close proximity (within 5 miles) to two or more existing OHS programs and would not improve the distribution of cardiovascular services within Maryland.

All applicants are designated as Stroke Centers by Maryland Institute for Emergency Medical Services Systems (MIEMSS); AAMC, HCH, JHBMC, and SAH are certified as Advanced Stroke Centers by the Joint Commission (JC). Accreditation of Disease-Specific Care Programs by the Joint Commission varies among the applicants. The vascular surgery programs at AAMC, BWMC, JHBMC, and SAH are accredited by the Intersocietal Commission for the Accreditation of Vascular Laboratories. AAMC, SGAH, SMHC, and SAH are accredited Chest Pain Centers, only SAH has Cycle II accreditation with PCI designation (the period of the hospital's Cycle I accreditation was from 12/18/2003 to 12/17/2006). Cardiac and pulmonary rehabilitation services at AAMC, BWMC, SMHC, and SAH are certified by the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR). JHBMC has an AACVPR certified pulmonary rehabilitation program, and SGAH has an AACVPR certified cardiac rehabilitation program.

**Table 17. Certified and Accredited Cardiovascular Programs at Applicant Hospitals.**

|   | <b>AAMC</b> | <b>BWMC</b> | <b>HCH</b> | <b>JHBMC</b> | <b>SGAH</b> | <b>SMHC</b> | <b>SAH</b> |
|---|-------------|-------------|------------|--------------|-------------|-------------|------------|
| <b>Joint Commission</b>                   |             |             |            |              |             |             |            |
| Acute Coronary Syndrome                   |             |             | Accredited |              | Accredited  |             | Accredited |
| Acute Myocardial Infarction               |             |             | Accredited |              | Accredited  |             | Accredited |
| Coronary Artery Disease                   |             |             | Accredited |              | Accredited  |             | Accredited |
| Heart Failure Center                      |             |             | Accredited |              | Accredited  |             | Accredited |
| Ischemic Heart Disease                    |             |             | Accredited |              | Accredited  |             | Accredited |
| Stroke Center, Advanced                   | Certified   |             | Certified  | Certified    |             |             | Certified  |
| Vascular Surgery                          |             |             | Accredited | Accredited   | Accredited  |             | Accredited |
| <b>MIEMSS<sup>1</sup>Stroke Center</b>    | Designated  | Designated  | Designated | Designated   | Designated  | Designated  | Designated |
| <b>AACVPR<sup>2</sup></b>                 |             |             |            |              |             |             |            |
| Cardiac Rehabilitation                    | Certified   | Certified   |            |              | Certified   | Certified   | Certified  |
| Pulmonary Rehabilitation                  | Certified   | Certified   |            | Certified    |             | Certified   | Certified  |
| <b>SCPC<sup>3</sup></b>                   |             |             |            |              |             |             |            |
| Chest Pain Center - Cycle I               | Accredited  |             |            |              | Accredited  | Accredited  | Accredited |
| Chest Pain Center - Cycle II              |             |             |            |              | Pending     | Pending     | Accredited |
| PCI Designation                           |             |             |            |              | Pending     |             | Yes        |
| <b>ICAVL<sup>4</sup> Vascular Surgery</b> | Accredited  | Accredited  |            | Accredited   |             |             | Accredited |

<sup>1</sup> Maryland Institute for Emergency Medical Services Systems-designated Primary Stroke Center

<sup>2</sup> American Association of Cardiovascular and Pulmonary Rehabilitation

<sup>3</sup> Society of Chest Pain Centers

<sup>4</sup> Intersocietal Commission for the Accreditation of Vascular Laboratories

***(b) An applicant's potential to increase access to PCI services for minorities and medically underserved populations;***

Response of Applicants

AAMC

According to AAMC, during FY 2007, 71% of its emergency department patients (73,512) were Caucasian/white, 23% African-American, 4% Hispanic, and 1% Asian. Among all patient services provided, 6,838 (9%) were Medicaid paid, 10,315 (14%) were self pay, and 3,788 (5%) were classified as other/unknown. These 20,941 patients constitute 28.4% of total discharges and largely represent the uninsured and medically underserved. AAMC notes that in Anne Arundel County, minorities comprise approximately 20% of the population and account for 50% of the 38,000 adult residents without medical insurance.

AAMC reports that it collaborates with the Lighthouse Shelter and with a group of hospital physicians and nurses in operating the Annapolis Outreach Center, a free clinic in a medically underserved area that provides medical care to the homeless. In 2007, the medical staff contributed to 4,902 appointments – 40% of patients were Hispanic and 38% were African-American. The Center provided care to 10-12% of the county's 38,000 uninsured. Sixty-six percent (66%) of these patients reside in either of two Annapolis ZIP Codes, one of which has a significant Hispanic population. AAMC is considering opening a second center.

Based on an AAMC-sponsored survey, the hospital concluded that Queen Anne's County residents are underserved with respect to access to cardiovascular services. The hospital's new center on Kent Island will open in Spring 2008 and will offer cardiology and vascular surgery services.<sup>25</sup> AAMC's Dare to Care initiative, a free vascular screening program currently available in Anne Arundel County will be replicated at the new facility.

AAMC notes the distances that patients from Anne Arundel County, the Eastern Shore, and Southern Maryland currently must travel to access npPCI services. AAMC believes that opening an npPCI program at the hospital would complement the hospital's expansion to Kent Island, the work of the Annapolis Outreach Center, and the commitment to caring for minorities and the uninsured as evidenced by the emergency department records.

BWMC

BWMC indicates that during FY 2007, its emergency department saw more than 86,000 patients; 32% represented various minorities and 29% received Medicaid or medical assistance, or were self-paying. The hospital projects that the number of emergency department visits will increase and that the hospital will treat a growing number of unregistered immigrants. Cardiovascular problems account for 20% of the hospital's inpatient admissions.

According to BWMC, most (80%) of its total patient population comes from 10 ZIP Codes, with minorities constituting 23% of the total population in those ZIP Codes. Overall,

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<sup>25</sup> Facility opened to the public during April 2008

minorities comprise 20% of Anne Arundel County's population. Within this 10 ZIP Code area, which BWMC defines as the hospital's primary service area, 18% of the population receives Medicaid or medical assistance, or are self-paying. BWMC cites a county health department report<sup>26</sup> indicating that 66% of the county's Medicaid recipients reside in five ZIP Codes, four of which are in the hospital-defined primary service area.

The hospital reports that data collected by People's Community Health Center (PCHC), a health clinic operating in two of the ZIP Codes comprising the BWMC-defined primary service area, indicate that the population of these two ZIP Codes exceeds 80,000, including 25,534 Medicaid recipients and 32,000 uninsured. Approximately 28,530 people reside in a government-funded housing complex within this area; 26% of these residents have annual income at or below the federal poverty level.

BWMC describes a variety of hospital outreach programs targeting minorities and the medically underserved. The hospital collaborates with Zeta Phi Beta sorority to offer pre-natal education to pregnant women. BWMC also participates in a county program, Residents Access to a Coalition of Health (REACH) that targets uninsured residents 19 to 64 years of age. The hospital and both cardiology practices at BWMC treat REACH patients; both practices accept medical assistance and treat patients who lack insurance. BWMC conducts blood pressure, vascular, cholesterol, and body mass index screening at churches, community centers, and other venues. During CY 2007, the hospital conducted 2,200 screenings.

The hospital notes that minority and medically underserved residents are concentrated within BWMC's service area and would benefit by not having to travel to more distant facilities if the hospital receives an npPCI research waiver. Currently, seven of the 10 ZIP Codes in its self-defined service area are served by a single bus route, which can be accessed by residents of the other three ZIP Codes with a single transfer. The hospital's screening programs can identify people who might benefit from npPCI. The Community Mission Committee of the BWMC Board of Directors oversees the hospital's community benefit mission by identifying unmet needs and funding selected programs. BWMC states that if it receives an npPCI research waiver, the committee will consider cardiovascular services in the context of the unmet needs program.

## HCH

HCH states that it serves a high volume of minority patients – 66% of the overall patient population, 51% of cardiac patients, and 59% of emergency department patients are non-white. The hospital's analysis indicates that 70% of HCH's cardiac patients come from Montgomery County and that they constitute 17% of the county's cardiac care market. Based on demographic data for FY 2007, HCH provides care for 24% of the county's African-American cardiac patients and 29% of the Hispanic cardiac patients. Overall, the hospital cares for 22% of the county's minority cardiac patients.

The hospital indicated that during FY 2006, it provided 50% more charity care than any other hospital in the Metropolitan Washington Regional Service Area. Based on the hospital's market analysis, 10,008 Montgomery County residents received cardiac services during FY

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<sup>26</sup> Anne Arundel County Department of Health, Infant Mortality Update 1997-2001



2007; 496 were self-pay and 20 received charity care. HCH provided care to 1,665 (17%) of the county's cardiac patients. Of this total, 92 (5.5%) were self payers and 18 (1.1%) were charity patients; the two groups accounted for 19% of the county's self-payers and 90% of the county's charity cases.

HCH reports drawing 44% of inpatients from a densely populated core area in which the population grew by 8% between 1990 and 2000 according to Census data. The number of foreign-born residents increased by more than 37,000 (61%), and account for 31% of the core area population; 17% of the foreign-born speak English "less than very well." Montgomery County has identified "cultural access" as a high priority in the jurisdiction's Community Health Improvement Plan.

According to HCH, last year it provided physician services and a medical home to 1,450 uninsured adults through more than 6,200 visits. Many of these patients presented with a variety of chronic health problems, including a large number requiring cardiac services. Since 2001, the hospital has operated an ethnic health promotion program that trains health promoters and targets racial and ethnic minority populations that have reduced access to care due to financial and/or geographic barriers, cultural practices, and/or lack of knowledge of the U.S. health care system. Health promoters are drawn from African-American, Asian, Hispanic, and Russian-American communities, and establish trust, raise awareness about early disease detection, and offer support during screening, diagnosis, and treatment. Because of the success of the program, HCH has received a grant from the Maryland Minority Office of Technical Assistance to train ethnic health promoters from throughout the State.

HCH described Senior Fit, a hospital-based physical activity program, which was recognized as one of 10 exemplary programs by the National Council on Aging. Senior Fit is one of three programs selected for inclusion in a study of intervention effectiveness. The hospital also supports a faith community nursing program in 54 congregations (85,000 members) that reach minority and underserved communities. The hospital expects that receipt of an npPCI research waiver would expand the range of services that HCH could offer to these communities.

## JHBMC

JHBMC reports that minorities comprised 34.2% of inpatients treated at JHBMC during CY 2005 and 37.1% of inpatients during CY 2007; most were African-American. The proportion of Hispanic inpatients increased from 5.1% during 2005 to 6.4% during 2007. During 2007, 26.4% of inpatients received Medicaid benefits and 16.2% were classified as self-pay. JHBMC cites a recent report<sup>27</sup> as indicating that the hospital provided \$44.8 million in uncompensated care, which reflects both charity care and bad debt, during FY 2006. The value of uncompensated care provided during FY 2006 by the other six applicants for an npPCI research waiver ranged from \$15.2 million to \$23.3 million according to JHBMC.

The hospital states, without citing the relevant source(s), that "[i]n past reviews for OHS/PTCA services, the MHCC has utilized a hospital's historical provision of services to medically underserved and minority populations as a strong indicator for their future provision of

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<sup>27</sup> Health Services Cost Review Commission, Maryland Hospital Community Benefit Report FY 2006, June 8, 2007

services to these targeted populations if a new cardiac program were to be established.” For the period from January 1 to September 30, 2007, JHBMC reported providing care for 8,651 inpatients who met the hospital’s criteria for both minority (i.e., non-Caucasian) and medically underserved (i.e., self-pay or Medicaid). These patients constituted 55% of all inpatients cared for during this nine month period. During the same period, JHBMC reports that AAMC and BWMC respectively cared for 4,447 (27.1%) and 3,713 (27.4%) patients who met both of these criteria. JHBMC is confident that, if granted an npPCI research waiver, it will be able to provide the service to more minority and medically underserved patients than would any other applicant in Central Maryland.

## SGAH

SGAH states that, for the 12-month period ending September 30, 2007, it treated more minority patients for ST-segment elevation myocardial infarction (STEMI) on a percentage basis than did like hospitals or all hospitals in the U.S.<sup>28</sup> African-Americans accounted for 11% of the SGAH cases, 10% were Hispanic, 10% Asian, and 6% other. In contrast, among STEMI cases treated at like hospitals, 9% of patients were African-American, 4% Hispanic, 2% Asian, and 3% other. The corresponding percentages were less when data from all registry hospitals were considered. Similar patterns were observed among non-STEMI (NSTEMI) patients, with SGAH treating proportionally more patients than either like hospitals or all hospitals. For the same 12-month period, 15% of SGAH’s NSTEMI patients were African American, 5% Hispanic, 6% Asian, and 10% other. During this 12-month period, minorities comprised 37% of the hospital’s STEMI cases and 36% of the NSTEMIs.

SGAH indicates that its total service area, which includes Mount Airy, Germantown, Gaithersburg, Rockville, and parts of Silver Spring, is undergoing rapid demographic changes. During 2007, whites comprised 63.8% of the population in the total service area, Asians 14.1%, African-Americans 12.7%, and others 5.2%. By 2012, each respective group is expected to comprise 60%, 15.8%, 13.3%, and 6% of the service area population. In addition, Native Americans and Pacific Islanders respectively make up 0.3% and 0.1% of the current population. These percentage contributions are not expected to change with regard to the 2012 population projection.

Adventist HealthCare, Inc., SGAH’s parent entity, established an independent Center on Health Disparities that addresses issues affecting the underserved. SGAH indicates that its Health and Wellness Department provides a variety of screening and other services (e.g., fitness programs, mammograms, and early heart disease detection) to minorities and medically underserved. The hospital states that patients treated at SGAH reflect the diversity and changing demographics of the larger community. Already, the hospital provides pPCI services to a greater proportion of minority patients than similar hospitals. SGAH states that receipt of an npPCI

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<sup>28</sup> The hospital cites data from the American College of Cardiology (ACC) ACTION Registry®, which is a national, voluntary data registry that gathers hospital-specific information on the treatment, care, and outcomes for patients with myocardial infarction. Like hospitals are defined by the ACC as hospitals with the same on-site cardiac facilities (e.g., catheterization laboratory, open-heart surgery) as the hospital of interest based on information filed with the American Heart Association.

research waiver would enhance its ability to provide cardiovascular services to minorities and the medically underserved in the Metropolitan Washington Regional Service Area.

### SMHC

SMHC states that 70% of its inpatients were non-white, compared to 41% of inpatients at SGAH, and 66% of inpatients at HCH. The hospital refers to Health Services Cost Review Commission inpatient case mix data for 2006 as indicating that 61% of the hospital's PCI patients represented minorities, compared to 43% at HCH and 28% at SGAH. SMHC anticipates that a similar proportion of minority patients would be treated under an npPCI research waiver. The hospital examined the same data to determine the number of minority patients that received cardiovascular care at each of the three hospitals. SMHC states that it treated nearly twice as many cardiac care patients (4,165) as SGAH (2,404) or HCH (2,403). Non-whites comprised 74.7%, 34.8%, and 50.1% of the respective totals.

Based on 2007 population data, SMHC states that there were 198,060 non-white persons greater than age 14 years residing in the hospital's self-defined Access Improvement ZIP Codes (AIZC). According to SMHC, the corresponding totals for SGAH and HCH were 125,869 and 140,779, respectively. The non-white population projections for 2012 follow the same pattern: SMHC (235,608); SGAH (149,598); and HCH (160,026). Between 2007 and 2012, the non-white adult population in the SMHC AIZC is expected to increase 19%. An increase of 18.9% is expected for the SGAH AIZC and 13.7% for the HCH AIZC.

SMHC observes that although hospital rates in Maryland provide for care of the uninsured and those unable to afford care, there are no comparable programs to reimburse physicians who provide free care. Consequently, a patient whose source of payment is Medicaid, charity, or self pay may have difficulty obtaining physician services. These people are more likely to seek care at a hospital emergency department, particularly those with chronic conditions like heart disease. According to SMHC, the HSCRC 2006 data indicate that 486 (12%) of its cardiovascular patients, 290 (12%) of those at HCH, and 269 (11%) of those at SGAH received services assigned to Medicaid, charity care, or self-pay. SMHC expects that its already substantial commitment to caring for minorities and the medically underserved will be reflected in the hospital's ability to improve access to npPCI procedures under the research waiver program.

The hospital states that it offers a diverse array of outreach and other programs that target minority and underserved patients, and that these provide accessible routes of access to cardiac and other services. The hospital reports establishing Community Family Practice Centers in Fort Washington, Upper Marlboro, Clinton, and Waldorf that are staffed by physicians and other health care professionals representing various racial and ethnic groups. Site selection was based on need; a large, but unspecified proportion of these patients receive Medical Assistance.

SMHC indicates that it regularly provides a variety of health screening activities at SMHC and via mobile and off-site programs. Various community education programs are based in the Cardiac Risk Reduction Center, the Cardiac and Respiratory Education Support Group, Cardiopulmonary Rehabilitation Education Program, Stress Management Workshop, Heart

Failure Program, and Early Heart Attack Care Program. Other initiatives include a Fresh Start smoking cessation program in conjunction with the American Cancer Society, Ask-The-Doctor and Ask-A-Health-Professional programs, support for mall walker programs in Prince George's and Charles Counties, and coordination of an Annual Festival of Health in Waldorf.

## SAH

According to SAH-provided data, during CY 2006 and 2007 the hospital provided pPCI to a total of 152 patients, 48 (32%) of whom were non-white. During 2006, African-Americans comprised 28.9% of the 76 patients receiving pPCI; other, unspecified, racial groups accounted for 2.6% of the total cases. African-Americans made up 25% of the 76 pPCI procedures performed during 2007, with unspecified others and Asians accounting for 5.3% and 1.3% of the total, respectively. The same hospital-provided data indicated that during 2006, 17 (22.4%) of the 76 pPCI patients met the definition of being medically underserved, i.e., the costs of services administered were ascribed to Medicaid, charity care, or self-pay. During 2007, 17.1% of the 76 pPCI patients at SAH were classified as medically underserved by these criteria.

SAH also presented in-hospital data on the race and ethnicity of patients transferred from the hospital to tertiary facilities for cardiac care. Between CY 2004 and 2007, SAH annually transferred between 312 and 457 cardiac patients. The proportion of non-white patients (including Hispanics) ranged from 27% to 38% annually. According to SAH, the proportion of transferred non-white cardiac patients is consistent with the demographics of the ZIP codes comprising the hospital-defined core service area, which indicate that 39.9% of residents are non-white and 45 years of age or older.

SAH states that it is committed to creating access to health care for the poor, uninsured, and medically underserved, noting that its investment in charity care and public benefit increased from \$7.2 million in 2000 to \$12.9 million in 2007. The hospital has established partnerships with houses of worship, non-profit organizations, and community groups to provide services (e.g., diagnostic screening), address racial disparities in health care, and promote health education. SAH is the site of the Baltimore Medical System, which provides affordable health care services to uninsured and underserved patients from the surrounding community and those treated in the hospital's emergency department. The hospital collaborates with St. Joseph Medical Center in a joint venture, Mission Health Partners, which will offer cardiac education and prevention outreach throughout the Baltimore metropolitan area.

SAH used FY 2007 data from the Maryland Hospital Association to compare emergency department visits for eight specific cardiovascular diagnoses among the seven npPCI research waiver applicants. SAH ranked second among the seven both in terms of the total number of visits for all cardiovascular diagnoses and the total number of minority visits for the same diagnoses. Relative to the proposed npPCI research program, SAH ranked second in terms of all visits and all minority patient visits for ischemic heart disease.

The hospital examined race and ethnicity, and payer data for all residents of the area SAH identified as the primary source of patients for its proposed npPCI research project. SAH found that minorities comprised 44.8% of the people in the target area who received pPCI services

during the 12 months ending September 30, 2007. Of the 1,715 pPCI patients, 637 (37.1%) were African-American and 131 (7.6%) represented other racial and ethnic groups. Among the 1,715 patients, 141 (8.2%) were Medicaid beneficiaries and 76 (4.4%) were self pay or received charity care. SAH notes that the medically underserved population in the npPCI target area (12.7% of the 1,715 pPCI patients) is smaller than the underserved population currently receiving pPCI services at SAH (30 [19.7%] of 152 patients), and attributes this to the growing reliance on the hospital by the underserved community.

SAH reports that in recent years, it has initiated a variety of programs to better understand and address disparities in access to health care services, and to provide outreach to minorities and the medically underserved. For the annual Red Dress Sunday program, SAH collaborates with churches throughout the Baltimore area to provide African-American women with information about heart disease and to conduct risk screening. Last year the program reached more than 50,000 women through more than 50 churches. This year the program expanded to include more than 65 churches in Prince George's and Montgomery Counties.

SAH states that its history of outreach and service to minorities and the medically underserved, including the performance of the hospital's current pPCI program reflects the commitment that it will extend to the proposed npPCI research project.

### Analysis and Findings

Potential to increase access to PCI services for minorities and medically underserved populations is one of the additional factors considered in this review. As noted previously, many patients do not receive evidence-based therapies according to current practice guidelines. Based on clinical data registries, it is estimated that 27% to 56% of patients with non-ST-elevation acute coronary syndrome (NSTEMI or unstable angina) do not receive diagnostic angiography. Further, 45% to 78% do not have revascularization procedures performed during the initial hospitalization. Researchers have reported poorer outcomes among these patients, who were found to have a higher prevalence of demographic characteristics such as African-American race or low socioeconomic status.<sup>29</sup>

Minority patients, African Americans in particular, are less likely than white patients to receive the evidence-based therapies and interventions recommended in national practice guidelines.<sup>30</sup> In a study of patients referred for diagnostic coronary angiography, researchers noted, "Despite an increasingly ethnically diverse US population, our current understanding of ethnic differences in the extent and severity of coronary artery disease (CAD) is based predominantly on white male populations."<sup>31</sup>

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<sup>29</sup> Chan MY, Becker RC, and Harrington RA. Noninvasive, medical management for non-ST-elevation acute coronary syndromes. *Am Heart J* 2008;155:397-407.

<sup>30</sup> Karve AM, Fang-Shu O, Lytle BL, and Peterson ED. Potential unintended financial consequences of pay-for-performance on the quality of care for minority patients. *Am Heart J* 2008;155:571-576.

<sup>31</sup> Shaw LJ, Shaw RE, Merz NB, et al. Impact of ethnicity and gender differences on angiographic coronary artery disease prevalence and in-hospital mortality in the American College of Cardiology – National Cardiovascular Data Registry. *Circulation* 2008;117:1787-1801.

The problem of racial and ethnic disparities in cardiovascular care is well-documented.<sup>32</sup> Strong and consistent evidence of these differences led the Institute of Medicine (IOM), the federal Agency for Healthcare Research and Quality (AHRQ), and the major cardiovascular societies in the United States to institute national campaigns to eliminate these inequities in care. Placing an emphasis on clinical research studies with more representative patient populations can help ensure the inclusion of minorities and reduce inappropriate variation in care. Future studies should simultaneously examine variables related to racial differences in the provision of cardiac care.<sup>33</sup> In addition to the demographic factors found in administrative databases, research trial databases allow for the examination of patient clinical characteristics and other possible sources of variability in the use of cardiac procedures (for example, refusal of procedures).<sup>34</sup>

A number of organizations are seeking to increase minority representation in medical research, including cardiovascular clinical trials. The National Institutes of Health (NIH) require that “women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.”<sup>35</sup> Professional societies have recognized the progress NIH has made in ensuring representation of women in clinical trials; however, investigators who do not apply for federal funding are not required to comply with this policy.<sup>36</sup> Efforts to encourage the inclusion of minorities include those of the National Medical Association, which represents African-American physicians and has established Project IMPACT (Increase Minority Participation and Awareness in Clinical Trials).

The factors that are likely to affect an applicant’s success in recruiting minority and underserved patients into the trial include the geographic distribution of these population groups and their recent utilization of the applicant hospital. Additionally, studies have found that minority groups are asked to participate in research less frequently, an issue that applicants must address.<sup>37</sup>

Each of the seven npPCI research waiver applicants states that it is committed to serving racially and ethnically diverse populations and to providing care for the uninsured and medically underserved. Consistent with these commitments, each describes a variety of outreach, education, and/or health screening programs that are directed toward minorities and the underserved. These programs are intended to improve health awareness, facilitate identification of risk factors, initiate risk reduction interventions, reduce cultural and financial barriers to

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<sup>32</sup> See for example, Smedley BD, Stith AY, and Nelson AR, ed. Committee on Understanding and Eliminating Racial and Ethnic Disparities in Health Care, Institute of Medicine. *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*. Washington, DC: National Academies Press, 2003.

<sup>33</sup> Rumsfeld JS, Peterson ED. Care disparities: Moving from gray to black and white. *J Am Coll Cardiol* 2005;45:79-81.

<sup>34</sup> Kressin NR, Peterson LA. Racial differences in the use of invasive cardiovascular procedures: Review of the literature and prescription for future research. *Ann Intern Med* 2001;135:352-366.

<sup>35</sup> This policy of the National Institutes of Health results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

<sup>36</sup> Alexander-Bridges M, Doan LL. Commentary: Increasing minority participation in clinical research: A white paper from the Endocrine Society. *Journal of Clinical Endocrinology & Metabolism* 2007;92:4557-4559.

<sup>37</sup> Braunstein JB, Sherber NS, Schulman SP, et al. Race, medical researcher distrust, perceived harm, and willingness to participate in cardiovascular prevention trials. *Medicine* 2008;87:1-9.

health care access, and facilitate the delivery of health care services to minorities and to the uninsured and underserved.

The commitment to caring for minorities, the uninsured, and the medically underserved is reflected in a variety of demographic data submitted by the applicants to demonstrate the diversity of the communities served. Demographic data are variously based on county level or hospital-defined service areas information, which confound hospital-to-hospital comparison. In addition, some hospitals provided data based on calendar year, some on fiscal year, and some on consecutive 12-month period. Discharge and hospital utilization data likewise span different periods and were drawn from in-hospital databases, Health Services Cost Review Commission data sets, and/or the ACC ACTION Registry®, a national risk-adjusted, outcomes-based quality improvement program database.

Table 18 indicates that the hospitals with the greatest proportion of African-American residents in their combined service areas are SMHC (62.7%), SAH (48.4%), JHBMC (44.6%), and HCH (32.2%). The hospitals with the greatest proportion of Asian residents in their combined service areas are SGAH (12.8%) and HCH (8.1%). Those with the greatest proportion of Hispanic residents are HCH (13.9%) and SGAH (13.9%). The hospitals with the greatest proportion of all minorities in their combined PSA/ESA are SMHC (75.8%), HCH (63.8%), SAH (58.3%), JHBMC (52.7%), and SGAH (46.3%). For these five hospitals, the proportion of all minorities in their primary and extended services areas was above the statewide average.

Table 19 shows the demographic characteristics of inpatients with cardiovascular-related diagnoses treated by each waiver applicant. Table 20 compares the service area population characteristics with the demographic characteristics of cardiovascular inpatients served by each hospital. SMHC served a cardiovascular inpatient population comparable to the demographic characteristics of its primary and extended service area. Although not as strongly correlated as SMHC, data reported for AAMC, HCH, SGAH, and SAH also indicates that the demographic characteristics of their cardiovascular patients reflect the composition of their service area population.

**Table 18. Current (2007) and Projected (2012) Total Population and Population by Race and Ethnicity (Hispanic) Within Each Applicant's Primary (PSA) and Extended (ESA) Service Area**

|              |                               | 2007    |      |           |      |           |      | 2012    |      |           |      |           |      |
|--------------|-------------------------------|---------|------|-----------|------|-----------|------|---------|------|-----------|------|-----------|------|
|              |                               | PSA     | %    | ESA       | %    | Total     | %    | PSA     | %    | ESA       | %    | Total     | %    |
| <b>AAMC</b>  | Total                         | 200,134 |      | 253,080   |      | 453,214   |      | 206,674 |      | 265,799   |      | 472,473   |      |
|              | White <sup>1</sup>            | 152,464 | 76.2 | 191,508   | 75.7 | 343,972   | 75.9 | 146,861 | 71.1 | 192,564   | 72.4 | 339,425   | 71.8 |
|              | African-American <sup>1</sup> | 26,088  | 13.0 | 34,937    | 13.8 | 61,025    | 13.5 | 31,400  | 15.2 | 40,273    | 15.2 | 71,673    | 15.2 |
|              | Asian <sup>1</sup>            | 4,636   | 2.3  | 7,440     | 2.9  | 12,076    | 2.7  | 5,857   | 2.8  | 9,091     | 3.4  | 14,948    | 3.2  |
|              | Other <sup>1,2</sup>          | 8,029   | 4.0  | 10,471    | 4.1  | 18,500    | 4.1  | 10,937  | 5.3  | 12,302    | 4.6  | 23,239    | 4.9  |
|              | Hispanic <sup>3</sup>         | 8,917   | 4.5  | 8,724     | 3.4  | 17,641    | 3.9  | 11,619  | 5.6  | 11,569    | 4.4  | 23,188    | 4.9  |
| <b>BWMC</b>  | Total                         | 169,878 |      | 149,229   |      | 319,107   |      | 175,796 |      | 156,415   |      | 332,211   |      |
|              | White <sup>1</sup>            | 127,054 | 74.8 | 110,323   | 73.9 | 237,377   | 74.4 | 127,940 | 72.8 | 110,981   | 71.0 | 238,921   | 71.9 |
|              | African-American <sup>1</sup> | 22,965  | 13.5 | 23,662    | 15.9 | 46,627    | 14.6 | 23,986  | 13.6 | 26,764    | 17.1 | 50,750    | 15.3 |
|              | Asian <sup>1</sup>            | 6,143   | 3.6  | 4,871     | 3.3  | 11,014    | 3.5  | 7,211   | 4.1  | 5,895     | 3.8  | 13,106    | 3.9  |
|              | Other <sup>1,2</sup>          | 7,731   | 4.6  | 5,779     | 3.9  | 13,510    | 4.2  | 9,089   | 5.2  | 6,790     | 4.3  | 15,879    | 4.8  |
|              | Hispanic <sup>3</sup>         | 5,985   | 3.5  | 4,594     | 3.1  | 10,579    | 3.3  | 7,570   | 4.3  | 5,985     | 3.8  | 13,555    | 4.1  |
| <b>HCH</b>   | Total                         | 403,753 |      | 1,132,717 |      | 1,536,470 |      | 422,462 |      | 1,195,161 |      | 1,617,623 |      |
|              | White <sup>1</sup>            | 147,663 | 36.6 | 407,769   | 36.0 | 555,432   | 36.1 | 144,088 | 34.1 | 388,504   | 32.5 | 532,592   | 32.9 |
|              | African-American <sup>1</sup> | 75,104  | 18.6 | 419,822   | 37.1 | 494,926   | 32.2 | 74,047  | 17.5 | 436,260   | 36.5 | 510,307   | 31.5 |
|              | Asian <sup>1</sup>            | 34,845  | 8.6  | 89,513    | 7.9  | 124,358   | 8.1  | 38,779  | 9.2  | 100,103   | 8.4  | 138,882   | 8.6  |
|              | Other <sup>1,2</sup>          | 55,096  | 13.6 | 92,795    | 8.2  | 147,891   | 9.6  | 60,818  | 14.4 | 111,637   | 9.3  | 172,455   | 10.7 |
|              | Hispanic <sup>3</sup>         | 91,045  | 22.5 | 122,818   | 10.8 | 213,863   | 13.9 | 104,730 | 24.8 | 158,657   | 13.3 | 263,387   | 16.3 |
| <b>JHBMC</b> | Total                         | 155,402 |      | 512,432   |      | 667,834   |      | 157,063 |      | 519,334   |      | 676,397   |      |
|              | White <sup>1</sup>            | 110,616 | 71.2 | 204,488   | 39.9 | 315,104   | 47.2 | 101,671 | 64.7 | 206,793   | 39.8 | 308,464   | 45.6 |
|              | African-American <sup>1</sup> | 30,115  | 19.4 | 268,062   | 52.3 | 298,177   | 44.6 | 38,152  | 24.3 | 265,439   | 51.1 | 303,591   | 44.9 |
|              | Asian <sup>1</sup>            | 2,768   | 1.8  | 13,402    | 2.6  | 16,170    | 2.4  | 3,563   | 2.3  | 15,555    | 3.0  | 19,118    | 2.8  |
|              | Other <sup>1,2</sup>          | 6,177   | 4.0  | 13,951    | 2.7  | 20,128    | 3.0  | 6,684   | 4.3  | 14,660    | 2.8  | 21,344    | 3.2  |
|              | Hispanic <sup>3</sup>         | 5,726   | 3.7  | 12,529    | 2.4  | 18,255    | 2.7  | 6,993   | 4.5  | 16,887    | 3.3  | 23,880    | 3.5  |



**Table 18. Continued.**

|             |                               | 2007    |      |         |      |         |      | 2012    |      |         |      |         |      |
|-------------|-------------------------------|---------|------|---------|------|---------|------|---------|------|---------|------|---------|------|
|             |                               | PSA     | %    | ESA     | %    | Total   | %    | PSA     | %    | ESA     | %    | Total   | %    |
| <b>SGAH</b> | Total                         | 296,531 |      | 231,754 |      | 528,285 |      | 314,951 |      | 244,326 |      | 559,277 |      |
|             | White <sup>1</sup>            | 157,359 | 53.1 | 126,301 | 54.5 | 283,660 | 53.7 | 155,834 | 49.5 | 122,544 | 50.2 | 278,378 | 49.8 |
|             | African-American <sup>1</sup> | 30,041  | 10.1 | 24,147  | 10.4 | 54,188  | 10.3 | 34,256  | 10.9 | 26,956  | 11.0 | 61,212  | 10.9 |
|             | Asian <sup>1</sup>            | 41,883  | 14.1 | 25,724  | 11.1 | 67,607  | 12.8 | 46,168  | 14.7 | 29,679  | 12.1 | 75,847  | 13.6 |
|             | Other <sup>1,2</sup>          | 26,958  | 9.1  | 22,210  | 9.6  | 49,168  | 9.3  | 30,246  | 9.6  | 25,612  | 10.5 | 55,858  | 10.0 |
|             | Hispanic <sup>3</sup>         | 40,290  | 13.6 | 33,372  | 14.4 | 73,662  | 13.9 | 48,447  | 15.4 | 39,535  | 16.2 | 87,982  | 15.7 |
| <b>SMHC</b> | Total                         | 266,009 |      | 237,465 |      | 503,474 |      | 277,454 |      | 259,259 |      | 536,713 |      |
|             | White <sup>1</sup>            | 32,474  | 12.2 | 89,144  | 37.5 | 121,618 | 24.2 | 32,842  | 11.8 | 89,863  | 34.7 | 122,705 | 22.9 |
|             | African-American <sup>1</sup> | 194,491 | 73.1 | 121,301 | 51.1 | 315,792 | 62.7 | 188,649 | 68.0 | 130,603 | 50.4 | 319,252 | 59.5 |
|             | Asian <sup>1</sup>            | 7,088   | 2.7  | 5,246   | 2.2  | 12,334  | 2.4  | 8,230   | 3.0  | 7,380   | 2.8  | 15,610  | 2.9  |
|             | Other <sup>1,2</sup>          | 15,020  | 5.6  | 11,118  | 4.7  | 26,138  | 5.2  | 20,914  | 7.5  | 14,882  | 5.7  | 35,796  | 6.7  |
|             | Hispanic <sup>3</sup>         | 16,936  | 6.4  | 10,656  | 4.5  | 27,592  | 5.5  | 26,819  | 9.7  | 16,531  | 6.4  | 43,350  | 8.1  |
| <b>SAH</b>  | Total                         | 194,831 |      | 402,864 |      | 597,695 |      | 194,987 |      | 410,417 |      | 605,404 |      |
|             | White <sup>1</sup>            | 74,930  | 38.5 | 174,294 | 43.3 | 249,224 | 41.7 | 76,686  | 39.3 | 172,889 | 42.1 | 249,575 | 41.2 |
|             | African-American <sup>1</sup> | 105,169 | 54.0 | 183,962 | 45.7 | 289,131 | 48.4 | 100,793 | 51.7 | 183,713 | 44.8 | 284,506 | 47.0 |
|             | Asian <sup>1</sup>            | 5,611   | 2.9  | 20,838  | 5.2  | 26,449  | 4.4  | 6,631   | 3.4  | 25,320  | 6.2  | 31,951  | 5.3  |
|             | Other <sup>1,2</sup>          | 4,849   | 2.5  | 13,111  | 3.3  | 17,960  | 3.0  | 5,017   | 2.6  | 14,296  | 3.5  | 19,313  | 3.2  |
|             | Hispanic <sup>3</sup>         | 4,272   | 2.2  | 10,659  | 2.6  | 14,931  | 2.5  | 5,860   | 3.0  | 14,199  | 3.5  | 20,059  | 3.3  |

Source: Spatial Insights, Inc., Bethesda, MD

<sup>1</sup> Non-Hispanic

<sup>2</sup> Other includes demographic groups: American Indian; Hawaiian/Pacific Islander; Other Race; and Multiple Race

<sup>3</sup> Hispanic includes demographic groups: Hispanic White; Hispanic Black; Hispanic American Indian; Hispanic Hawaiian/Pacific Islander; Hispanic Other Race; and Hispanic Multiple Race

**Table 19. Number of Inpatients with Cardiovascular-related Principal Diagnoses and Payer Source in Calendar Year 2006 at Applicant Hospitals. The Percentage (%) of Cardiac Care Patients by Payer Source, Race, and Ethnicity is Based on the Total Number of Cardiac Care Patients at Each Respective Hospital.**

|              |                               | Total     |      | Medicaid  |      | Self Pay  |     | Charity Care |     | All Other Payers |      |
|--------------|-------------------------------|-----------|------|-----------|------|-----------|-----|--------------|-----|------------------|------|
|              |                               | Inpatient | %    | Inpatient | %    | Inpatient | %   | Inpatient    | %   | Inpatient        | %    |
| <b>AAMC</b>  | White <sup>1</sup>            | 2091      | 79.2 | 43        | 1.6  | 62        | 2.3 | 0            | 0.0 | 1986             | 75.2 |
|              | African-American <sup>1</sup> | 503       | 19.0 | 35        | 1.3  | 53        | 2.0 | 1            | 0.0 | 414              | 15.7 |
|              | Asian <sup>1,2</sup>          | 13        | 0.5  | 2         | 0.1  | 3         | 0.1 | 0            | 0.0 | 8                | 0.3  |
|              | Other <sup>1,3</sup>          | 10        | 0.4  | 2         | 0.1  | 0         | 0.0 | 0            | 0.0 | 8                | 0.3  |
|              | Hispanic <sup>4</sup>         | 24        | 0.9  | 6         | 0.2  | 5         | 0.2 | 0            | 0.0 | 13               | 0.5  |
|              | Total                         | 2641      | -    | 88        | 3.3  | 123       | 4.7 | 1            | 0.0 | 2429             | 92.0 |
| <b>BWMC</b>  | White <sup>1</sup>            | 3089      | 82.8 | 77        | 2.1  | 95        | 2.5 | 0            | 0.0 | 2917             | 78.2 |
|              | African-American <sup>1</sup> | 529       | 14.2 | 37        | 1.0  | 33        | 0.9 | 0            | 0.0 | 459              | 12.3 |
|              | Asian <sup>1,2</sup>          | 40        | 1.1  | 4         | 0.1  | 6         | 0.2 | 0            | 0.0 | 30               | 0.8  |
|              | Other <sup>1,3</sup>          | 45        | 1.2  | 3         | 0.1  | 8         | 0.2 | 0            | 0.0 | 34               | 0.9  |
|              | Hispanic <sup>4</sup>         | 26        | 0.7  | 5         | 0.1  | 4         | 0.1 | 0            | 0.0 | 17               | 0.5  |
|              | Total                         | 3729      | -    | 126       | 3.4  | 146       | 3.9 | 0            | 0.0 | 3457             | 92.7 |
| <b>HCH</b>   | White <sup>1</sup>            | 1147      | 48.1 | 22        | 0.9  | 27        | 1.1 | 3            | 0.1 | 1095             | 45.9 |
|              | African-American <sup>1</sup> | 864       | 36.2 | 62        | 2.6  | 63        | 2.6 | 7            | 0.3 | 732              | 30.7 |
|              | Asian <sup>1,2</sup>          | 79        | 3.3  | 6         | 0.3  | 7         | 0.3 | 1            | 0.0 | 65               | 2.7  |
|              | Other <sup>1,3</sup>          | 139       | 5.8  | 15        | 0.6  | 16        | 0.7 | 3            | 0.1 | 105              | 4.4  |
|              | Hispanic <sup>4</sup>         | 157       | 6.6  | 27        | 1.1  | 18        | 0.8 | 10           | 0.4 | 102              | 4.3  |
|              | Total                         | 2386      | -    | 132       | 5.5  | 131       | 5.5 | 24           | 1.0 | 2099             | 88.0 |
| <b>JHBMC</b> | White <sup>1</sup>            | 2429      | 75.9 | 284       | 8.9  | 95        | 3.0 | 0            | 0.0 | 2050             | 64.0 |
|              | African-American <sup>1</sup> | 707       | 22.1 | 145       | 4.5  | 42        | 1.3 | 0            | 0.0 | 520              | 16.2 |
|              | Asian <sup>1,2</sup>          | 3         | 0.1  | 0         | 0.0  | 0         | 0.0 | 0            | 0.0 | 3                | 0.1  |
|              | Other <sup>1,3</sup>          | 37        | 1.2  | 6         | 0.2  | 8         | 0.2 | 0            | 0.0 | 23               | 0.7  |
|              | Hispanic <sup>4</sup>         | 26        | 0.8  | 7         | 0.2  | 8         | 0.2 | 0            | 0.0 | 11               | 0.3  |
|              | Total                         | 3202      | -    | 442       | 13.8 | 153       | 4.8 | 0            | 0.0 | 2607             | 81.4 |

Table 19. Continued.

|             |                               | Total     |      | Medicaid  |     | Self Pay  |     | Charity Care |     | All Other Payers |      |
|-------------|-------------------------------|-----------|------|-----------|-----|-----------|-----|--------------|-----|------------------|------|
|             |                               | Inpatient | %    | Inpatient | %   | Inpatient | %   | Inpatient    | %   | Inpatient        | %    |
| <b>SGAH</b> | White <sup>1</sup>            | 1476      | 62.1 | 27        | 1.1 | 54        | 2.3 | 2            | 0.1 | 1393             | 58.6 |
|             | African-American <sup>1</sup> | 475       | 20.0 | 47        | 2.0 | 37        | 1.6 | 0            | 0.0 | 391              | 16.4 |
|             | Asian <sup>1,2</sup>          | 143       | 6.0  | 14        | 0.6 | 13        | 0.5 | 1            | 0.0 | 115              | 4.8  |
|             | Other <sup>1,3</sup>          | 154       | 6.5  | 16        | 0.7 | 10        | 0.4 | 0            | 0.0 | 128              | 5.4  |
|             | Hispanic <sup>4</sup>         | 130       | 5.5  | 18        | 0.8 | 24        | 1.0 | 0            | 0.0 | 88               | 3.7  |
|             | Total                         | 2378      | -    | 122       | 5.1 | 138       | 5.8 | 3            | 0.1 | 2115             | 88.9 |
| <b>SMHC</b> | White <sup>1</sup>            | 1017      | 24.5 | 26        | 0.6 | 35        | 0.8 | 0            | 0.0 | 956              | 23.1 |
|             | African-American <sup>1</sup> | 3033      | 73.2 | 205       | 4.9 | 206       | 5.0 | 0            | 0.0 | 2622             | 63.3 |
|             | Asian <sup>1,2</sup>          | 44        | 1.1  | 2         | 0.0 | 2         | 0.0 | 0            | 0.0 | 40               | 1.0  |
|             | Other <sup>1,3</sup>          | 14        | 0.3  | 2         | 0.0 | 0         | 0.0 | 0            | 0.0 | 12               | 0.3  |
|             | Hispanic <sup>4</sup>         | 35        | 0.8  | 1         | 0.0 | 4         | 0.1 | 0            | 0.0 | 30               | 0.7  |
|             | Total                         | 4143      | -    | 236       | 5.7 | 247       | 6.0 | 0            | 0.0 | 3660             | 88.3 |
| <b>SAH</b>  | White <sup>1</sup>            | 2090      | 56.2 | 87        | 2.3 | 47        | 1.3 | 35           | 0.9 | 1921             | 51.7 |
|             | African-American <sup>1</sup> | 1575      | 42.4 | 177       | 4.8 | 62        | 1.7 | 34           | 0.9 | 1302             | 35.0 |
|             | Asian <sup>1,2</sup>          | 14        | 0.4  | 2         | 0.1 | 1         | 0.0 | 0            | 0.0 | 11               | 0.3  |
|             | Other <sup>1,3</sup>          | 25        | 0.7  | 2         | 0.1 | 7         | 0.2 | 1            | 0.0 | 15               | 0.4  |
|             | Hispanic <sup>4</sup>         | 12        | 0.3  | 0         | 0.0 | 1         | 0.0 | 1            | 0.0 | 10               | 0.3  |
|             | Total                         | 3716      | -    | 268       | 7.2 | 118       | 3.2 | 71           | 1.9 | 3259             | 87.7 |

Source: Health Services Cost Review Commission, Maryland Hospital Discharge Data Set, CY 2006

1 Non-Hispanic

2 Includes demographic group: Pacific Islander

3 Includes demographic groups: Non-Hispanic American Indian; Non-Hispanic Other Race; and Non-Hispanic Biracial; and Non-Hispanic Unknown.

4 Includes demographic groups: Hispanic White; Hispanic African-American; Hispanic Asian/Pacific Islander; Hispanic American Indian; Hispanic Other Race; Hispanic Biracial; and Hispanic Unknown.

**Table 20. Percent Service Area Minority Population, Percent Cardiovascular Minority Inpatients, and Ratio of Cardiovascular Minority Inpatients to Service Area Minority Population**

| <b>Hospital</b> | <b>% Minority Population in Primary and Extended Service Area</b> | <b>% Cardiovascular Minority Inpatients</b> | <b>Ratio: Cardiovascular Minority Inpatients to Service Area Minority Population</b> |
|-----------------|---|---|--|
| <b>AAMC</b>     | 24.2%   | 20.8%                                       | 0.86   |
| <b>BWMC</b>     | 25.6%   | 17.2%                                       | 0.67   |
| <b>HCH</b>      | 63.8%   | 51.9%                                       | 0.81   |
| <b>JHBMC</b>    | 52.7%   | 24.2%                                       | 0.46   |
| <b>SGAH</b>     | 46.3%   | 38.0%                                       | 0.82   |
| <b>SMHC</b>     | 75.8%   | 75.4%                                       | 0.99   |
| <b>SAH</b>      | 58.3%   | 43.8%                                       | 0.75   |

In addition to the concern about the abilities of applicant hospitals to increase access to PCI services by racial and ethnic minorities, the Commission is also interested in assuring access by the medically underserved, i.e., the indigent and people without medical insurance. Table 19 presents the total number of cardiac care inpatients at each applicant hospital during 2006. The data are based on all patients 17 years of age and older with a cardiovascular-related principal diagnosis. Inpatient data is reported by ethnicity (Hispanic) and race (non-Hispanic).<sup>38</sup> Combining charity care and self-pay as approximate measures of services provided to uninsured inpatients (Table 19), HCH (6.5%), SGAH (5.9%), and SMHC (6.0%) were above the average for the group (5.3%). When Medicaid billing data, an approximate measure of services to individuals who are low-income, are combined with charity care and self-pay data, JHBMC (18.6%) was well above the applicant average (11.6%). SAH (12.3%) and HCH (12.0%) were slightly above the average. BWMC (7.3%) and AAMC (8.0%) were the lowest.

<sup>38</sup>Demographic groups are comprised of Non-Hispanic White, Non-Hispanic Black, Non-Hispanic Asian/Pacific Islander, Non-Hispanic Other, which includes Non-Hispanic American Indian, Non-Hispanic Other Race, and Non-Hispanic Biracial, and Non-Hispanic Unknown. The Hispanic data include Hispanic White, Hispanic African-American, Hispanic Asian/Pacific Islander, Hispanic American Indian, Hispanic Other Race, and Hispanic Biracial, and Hispanic Unknown.

*(c) An applicant's ability and commitment to serve as a site for conducting research;*

Response of Applicants

AAMC

AAMC states that it has engaged in diversified medical research since the 1980s, and established an Institutional Review Board (IRB) in the mid-1990s that serves not only the hospital, but also medical staff involved in office-based protocols. Research oversight is based in the Research Department, which manages the IRB; the department's director serves as the Research Integrity Officer and Human Subjects Administrator. The Clinical Trials Department is responsible for the implementation, coordination and management of clinical studies in oncology. These two departments are integral components of the AAMC Research Institute, which was formed in 2007 to provide oversight to investigators throughout the institution, conduct outcomes research, coordinate resources between and among clinical and administrative departments, apply for research grants, and build relationships with potential research sponsors.

The hospital reports that in 2006, it entered into a research agreement with Johns Hopkins University and Johns Hopkins Hospital (Sidney Kimmel Comprehensive Cancer Center) to provide AAMC with greater access to clinical trials and research resources and expertise. The agreement is being expanded to foster collaboration in areas unrelated to cancer, and the two organizations are jointly recruiting staff to facilitate liaison between entities.

According to AAMC, between 2002 and 2004, it participated in a multi-center study with patient randomization to evaluate a cervical disc prosthesis; 3 hospital physicians enrolled 33 patients. A multi-center observational study without patient randomization that began in 2005 was completed in May 2008. The study compared use of an assessment device in breast surgery to pathological examination to evaluate surgical procedures, and involved 5 physicians and 119 patients. A multi-center study of radiation therapy in treating breast cancer was begun in 2005 and continues. Patients are randomized to treatment by 6 AAMC physicians; 6 patients have been enrolled. Another multi-center study, started in 2006, is examining the safety and efficacy of a carotid implant device. This trial does not require patient randomization; 4 physicians are participating and 24 patients have been enrolled. A prospective study without randomization also began in 2006. Five physicians have enrolled 21 patients in a study of carotid stenting.

AAMC has identified a registered nurse to fill "the newly created full-time position of Cardiac Program Coordinator dedicated solely to the management of the study." The hospital also stated that a second nurse is currently "devoting 60% of her work effort towards cardiovascular clinical data collection, including "establishing a new customized, electronic data repository for primary and non-primary PCI data, ... designed to ensure data quality before the information is entered into the Sextant registry." The on-site C-PORT E study team will have access to the resources and expertise of the AAMC Research Institute. Jonathan Altschuler, M.D. will serve as the on-site Principal Investigator for the study. AAMC will provide two finance staff trained in submitting billing information.

## BWMC

BWMC indicates that it recently completed a multi-center prospective study without patient randomization of a therapeutic agent for treating diabetics; 12 patients were recruited by 2 participating physicians. During 2006, the hospital conducted a survey of 199 randomly selected emergency department users as part of a multi-center study; there was one on-site investigator. Two ongoing multi-center studies began at BWMC during 2006. In one, 51 patients were enrolled in an ongoing prospective study of surgical intervention in the treatment of degenerative disc disease. The other uses a randomization design to compare physician access to information from implanted cardiac devices transmitted via the internet to access to information obtained by in-office device monitoring. One physician has enrolled 17 patients. An ongoing epidemiologic study to monitor hip fracture sequelae in men began in 2007; two physicians have enrolled 2 patients.

BWMC, a member of the University of Maryland Medical System (UMMS), reports that it is collaborating in a variety of ways with the larger institution to facilitate clinical research. In 2006, BWMC established a Human Subjects Review Committee (HSRC) to review all proposals for research within the hospital, monitor procedures to obtain informed consent, regularly review and follow-up on all approved studies, and ensure that researchers report emerging problems, adverse events and/or procedural changes to the committee. To review study protocols, BWMC relies on external IRBs, or the University of Maryland School of Medicine's IRB for protocols that have a faculty member as a principal investigator. The University of Maryland IRB will review the C-PORT E study protocols, if the hospital receives a research waiver. BWMC states that the University of Maryland IRB includes non-scientists, and non-affiliated and community members; some current IRB members reside in Anne Arundel County. The HSRC will monitor patient enrollment and impact of the study on the hospital.

The hospital states that the Cardiac Leadership Council, which is appointed by UMMS and comprised of cardiologists from both BWMC and University of Maryland Medical Center (UMMC), will help guide the work of the study team. The UMMC Division of Cardiology will assist the BWMC group in meeting the C-PORT E institutional and physician resource requirements, and will hire, under contract with BWMC, two data coordinators. BWMC states that the coordinators will be dedicated exclusively to this study and located on-site at BWMC. Drs. Samuel Yoon (BWMC) and Peter Reyes (UMMC) will serve as on-site Co-Principal Investigators for the C-PORT E study.

BWMC's president states that the hospital is committed to hiring, training and supervising the research nurse coordinators, data managers and business office staff necessary to participate in the C-PORT E study. The hospital will add a billing coordinator and train a back up billing coordinator. BWMC intends to add a second cardiac catheterization laboratory if it receives a research waiver from the Commission. This space will include prep and recovery areas that initially will be embedded in the existing CCU. BWMC will provide staff and staff training for these services. UMMC will provide training and mentoring for BWMC technical staff as the hospital's PCI program expands. Each year, the two institutions will jointly sponsor at least four Continuing Medical Education programs and two professional development programs for cardiology and internal medicine physicians at BWMC, and for emergency

medicine physicians in the community. Each year, two of the CME programs will be related to the study or the study population.

### HCH

HCH indicates that it is a teaching hospital with a long-standing commitment to education, research, and innovation, and participated in the original (1996) C-PORT study that compared pPCI and thrombolytic therapy in the treatment of STEMI patients. The hospital is committed to meeting all of the C-PORT E study participation requirements, including payment of the annual participation fee. HCH reports that the current staff of the hospital's research program consists of 1.0 FTE Manager, 2.0 FTE Study Coordinators, 1.0 FTE Research Associate and 1.0 FTE Research Assistant. The hospital anticipates hiring at least 1.5 FTEs to engage in data collection and will cross-train additional staff members to collect patient data as well as clinical and billing data from other facilities. Dr. Daniel Woronow will serve as on-site Principal Investigator for the C-PORT E study. HCH will train at least two employees to collect the billing information.

HCH reported initiating four clinical studies during 2007; all have been completed. One randomized patients to assess telephone monitoring systems for symptom management among cancer patients. Nine physicians enrolled 76 patients in this multi-center study. An observational study used a randomization design to evaluate nurse working conditions relative to medication administration safety. Two HCH investigators enrolled 69 participants. A similar study evaluated hand hygiene guidelines as part of a multi-center study with randomization; a total of 27 participants were enrolled. An ongoing multi-center study without randomization begun in 2004 is examining interventions for the early diagnosis and treatment of lung cancer; 228 patients have been recruited at HCH. In 2005, one investigator enrolled 42 patients in a single center study without randomization to assess the utility and patient acceptance of a wireless endoscope.

### JHBMC

JHBMC reports having a long history of conducting clinical research, ranging from acute interventions to long-term follow-up studies, including seminal research on "clot-busting" therapy for treating patients with acute myocardial infarction (AMI). The protocol called for the emergent transfer of AMI patients to the hospital's CCL for diagnostic cardiac catheterization and tPA administration. JHBMC also participated in other studies involving AMI patients, including the original (1996) C-PORT study comparing pPCI and thrombolytic therapy in the treatment of STEMI patients.

JHBMC states that its General Clinical Research Center (GCRC) will facilitate follow-up of patients enrolled in the C-PORT E study, in part by providing trained research nurses to manage the process and by providing additional guidance and resources in support of the study. JHBMC reports that the hospital will add 2.0 additional RN FTEs to directly support the study nurses within the existing framework of the GCRC. These FTEs (together with existing resources) will be scheduled so that coverage is provided seven days/week on day and evening shifts. Dr. Jeffrey C. Trost will serve as on-site Principal Investigator for the C-PORT E study.

The hospital will provide 1.0 FTE billing coordinator at JHBMC or JHH as well as a back up billing coordinator.

The hospital describes a multi-center, randomized placebo-controlled study in which JHBMC participated from 1997 through 2003. The study examined the efficacy of angiotensin converting enzyme (ACE) inhibitors in certain patients with prior myocardial infarction. Four JHBMC physicians enrolled 82 patients. A multi-center trial with patient randomization began in 2003 and will be completed in 2008. This study examines diabetes medications among patients randomized to PCI or coronary artery bypass grafting. The one on-site investigator has enrolled 13 patients. A multi-center randomized, double-blind study of the effects of anti-hypertensive agents on left ventricular mass began in 2005 and will end in 2008. Six physicians have enrolled 14 JHBMC patients. A pilot interventional study of an oral antioxidant treatment for reducing oxidative stress began in 2006 and will end in 2009. Three physicians have enrolled 7 patients. Another multi-center study that is expected to be completed in 2009 uses a randomization protocol to evaluate the effects of a pharmacological agent on hospitalized heart failure patients. The 10 participating JHBMC physicians have enrolled 5 patients.

### SGAH

SGAH submitted a letter from the hospital president stating that the hospital agrees to meet the “rigorous institutional, physician, and device criteria, and to commit the substantial financial, staffing, equipment, and other resources necessary to assure compliance with the study requirements and protocols.” The hospital also “commits to all of the participating site criteria, the participating physician criteria, the research commitment and data reporting requirements, and the State regulations and waivers.” Dr. Dennis Friedman will serve as on-site Principal Investigator for the C-PORT E study.

SGAH states that its independent Cardiac and Vascular Research Department includes a clinical nurse manager and 1.5 FTE nurses. An additional 1.5 FTE staff, including a full time nurse, will be hired by this department if the hospital receives a research waiver. The department’s staff will serve as research coordinators for the C-PORT E study, and will not be involved in patient care. The director of finance has identified two team members for the billing component of the study.

SGAH reports that in 2005 it began participating in a multi-center study with patient randomization that will end in 2009. Its 5 investigators have enrolled 16 patients in an assessment of the safety and efficacy of two medications for preventing stroke and embolism in certain patients. An ongoing multi-center study begun in 2006 uses a randomized, double-blind design to evaluate drug safety in osteoarthritis and rheumatoid arthritis patients with or at high risk for cardiovascular disease. Six SGAH physicians have enrolled 13 patients. Another ongoing multi-center study of clinical outcomes begun in 2006 randomizes cardiac implant patients to drug treatment regimes. The 6 on-site investigators have enrolled 11 patients. Three investigators have enrolled 12 patients in an ongoing multi-center post-market evaluation of coronary implants. A multi-center registry begun in 2007 examines complication rates in patients undergoing cardiac implant device replacement; 2 physicians have enrolled 12 patients.



## SMHC

A letter from the president of SMHC states that the hospital is prepared to provide the staff and other resources necessary to participate in the study. Specifically, the hospital will add 2.0 FTEs to provide non-clinical staff support: 1.5 FTE employees dedicated to data collection and follow-up; and, 0.5 FTE to assist investigators in the consent process and perform other administrative responsibilities. One of the two additional FTEs will be a nurse and one will be a data collection specialist who is not a nurse. The hospital also expects to dedicate an administrative assistant to the PCI program (not included in the above FTEs). The current primary PCI coordinator will become the RN coordinator for pPCI and npPCI and supervise data collection. Dr. Roy Leiboff will serve as on-site Principal Investigator for the C-PORT E study. SMHC states that the hospital expects to hire 1 FTE for the Financial Department to gather financial follow-up data.

SMHC reported participating in an ongoing multi-center population-based case control study of factors contributing to stroke in young adults. The registry began in 2003 and the hospital's one on-site investigator has enrolled 1,160 patients. During 2002, the hospital initiated a single center study of carotid stenting without patient randomization. The study ended in 2006 with 2 investigators enrolling 80 patients. A multi-center study without patient randomization was conducted at SMHC from 2002 through 2006. The one participating physician enrolled 70 patients to assess the safety of a mammary prosthesis. A multi-center study without randomization that the hospital reported began in 2007 is examining the utility and applications of a carotid stent system. The 2 investigators have enrolled 80 patients. An ongoing multi-center study without patient randomization is assessing the benefits of surgical treatment of degenerative disc disease. The one participating physician has enrolled 25 patients.

## SAH

SAH states that it is committed to participating in the C-PORT E study, noting that it was the first community hospital to enroll in the original (1996) C-PORT study that compared pPCI and thrombolytic therapy in the treatment of STEMI patients. SAH is currently recruiting for a (1 FTE) Cardiovascular Data Coordinator who will be responsible for both pPCI and npPCI data collection and management. The hospital's current CCL pPCI data collection policy states that the Data Coordinator oversees data input and timelines, and coordinates with the CCL RN to collect and input data. The CCL RN (5 FTEs) delivering care to the patient is responsible for all initial hospital procedure data, complications data and 6-week follow up. Dr. Stephen Plantholt will serve as on-site Principal Investigator for the C-PORT E study. SAH will hire a 1.0 FTE billing coordinator and cross-train existing data analysts in the Clinical Research Center with the duties of the billing coordinator.

SAH reports establishing a Clinical Research Center (CRC) in 1998 to improve the health of patients and the community through accessible high-quality health care, research, and education. The CRC has experience conducting phase II, III, and IV clinical trials in multiple therapeutic areas. This involvement ranges from trial oversight and support to actual study implementation and execution, including responsibility for regulatory compliance. The CRC

will hire a Clinical Data Coordinator to oversee data collection and follow-up of both the npPCI and pPCI programs.

SAH states that it participated in a multi-center study beginning in 2004 that randomized women with breast cancer to one of three chemotherapy regimens. The study is no longer enrolling patients; the one participating physician enrolled 12 women. A recently completed multi-center study that began in 2005 randomly assigned women with breast cancer to one of two irradiation treatments. The 6 investigators at SAH enrolled 30 patients. An ongoing multi-center study with patient randomization also began in 2005 and compares the safety and efficacy of a therapeutic agent given to leukemia patients. Among 6 investigators, 3 patients have been enrolled. Another ongoing multi-center study began at SAH during 2005. This prospective observational study examines the use of imaging to screen high-risk smokers for lung cancer. The 1 participating physician has recruited 1,143 patients. A multi-center study started in 2007 and is expected to be completed in 2011. This study randomizes patients to drug treatment for thromboembolism; the one on-site investigator has enrolled 3 patients at SAH.

### Analysis and Findings

The applicant hospitals were required to submit information about five recent studies (i.e., since 2000, including ongoing research that began prior to 2000) in which the hospital had participated. In addition to the summaries of recent clinical study participation, applicants were required to submit a letter from the hospital president indicating the institution's commitment to serve as a site for conducting research. Each applicant signed a letter of agreement with the C-PORT Principal Investigator that includes a commitment of resources necessary to comply with the study requirements related to data collection and follow-up: minimum of 1.5 FTEs devoted to the medical data requirements; medical data coordinator must be an RN; responsibilities cannot be added on to an existing position; two clinical data collection personnel must be trained to collect, enter, and transmit clinical data; a billing coordinator to generate, obtain, and enter uniform billing data; and two billing coordinators must be trained.

Clinical studies may use any of a large number of designs in addressing questions of safety, efficacy, benefit, and cost. Evidence that a hospital has experience participating in multi-center studies with patient randomization to treatment is considered one indicator of an applicant's ability to successfully participate in the C-PORT E study, particularly at the early outset of the study.

Although the timing antedates (1996-1999) the information required in the application, HCH, JHBMC, SGAH, and SAH noted their participation in the original C-PORT study, which was a multi-center clinical trial that randomized STEMI patients for treatment with pPCI or thrombolytic therapy. The database established for this study continued to serve as a data repository to which all seven applicants submitted observational data until the Commission's STEMI Registry was initiated in 2006.

Applicant-submitted information was reviewed to determine, in broad terms, the study design and medical focus, e.g., cardiovascular, cancer, etc., of the recent studies (Table 21).

**Table 21. Summary of Research Structure and Oversight and Recent Clinical Research Experience of Applicant Hospitals.**

|   | <b>AAMC</b>        | <b>BWMC</b>   | <b>HCH</b>       | <b>JHBMC</b>                            | <b>SGAH</b>                                    | <b>SMHC</b>                     | <b>SAH</b>                     |
|---|--------------------|---|------------------|---|--|---------------------------------|--------------------------------|
| <b>Research Structure and Oversight</b> |                    |   |                  |   |  |                                 |                                |
| <b>Organizational Structure</b>         | Research Institute | Human Subjects Review Committee (HSRC) <sup>A</sup> | Research Program | General Clinical Research Center (GCRC) | Clinical & Vascular Research Department (CVRD) | No Formal Centralized Structure | Clinical Research Center (CRC) |
| <b>Institutional Review Board</b>       | Internal           | UMd <sup>A</sup>                                    | Internal         | Internal                                | Internal                                       | Internal                        | Internal                       |
| <b>Research Experience</b>              |                    |   |                  |   |  |                                 |                                |
| <b>Study Designs</b>                    |                    |   |                  |   |  |                                 |                                |
| <b>Multi-center/Randomization</b>       | Yes                | Yes   | Yes              | Yes                                     | Yes  | -                               | Yes                            |
| <b>Multi-center/No Randomization</b>    | Yes                | Yes   | Yes              | -                                       | Yes  | Yes                             | -                              |
| <b>Observational/Other<sup>B</sup></b>  | Yes                | Yes   | Yes              | Yes                                     | Yes  | Yes                             | Yes                            |
| <b>Original C-PORT</b>                  | No                 | No  | Yes              | Yes                                     | Yes  | No                              | Yes                            |
| <b>Research Areas</b>                   |                    |   |                  |   |  |                                 |                                |
| <b>Cardiovascular</b>                   | Yes                | Yes   | -                | Yes                                     | Yes  | Yes                             | Yes                            |
| <b>Cancer</b>                           | Yes                | -   | Yes              | -                                       | -  | -                               | Yes                            |
| <b>Diabetes</b>                         | -                  | Yes   | -                | Yes                                     | -  | -                               | -                              |
| <b>Other</b>                            | Yes                | Yes   | Yes              | -                                       | -  | Yes                             | -                              |
| <b>Physicians/Study</b>                 | 3-6                | 1-2   | 1-9              | 1-10                                    | 2-6  | 1-2                             | 1-6                            |
| <b>Enrollment/Study</b>                 | 6-119              | 12-199  | 27-228           | 5-82                                    | 11-16  | 25-1,160                        | 3-1,143                        |

\* A dash (-) indicates that the five recent research studies reported by the applicant did not include the study design or research area indicated.

<sup>A</sup> The HSRC helps organize research efforts at BWMC. BWMC uses external IRBs, or, as for this study, the University of Maryland School of Medicine's IRB for protocols that have a faculty member as a principal investigator.

<sup>B</sup> Includes registries, prospective studies, single center studies with or without randomization, etc.

All of the applicants articulated commitments to engaging sufficient staff to successfully participate in the C-PORT E study. All state that clinical data management will be the responsibility of nurses.

Each applicant has the ability and has made the commitment to serve as a research site.

*(d) An applicant's demonstration of successful and timely acquisition of follow-up data on primary PCI patients;*

Response of Applicants

AAMC

AAMC describes a process that includes compilation of a patient log at the conclusion of each pPCI case. Each procedure is entered into the hospital's scheduling system for tracking, reporting, and reconciliation. Secure copies of the patient's chart are provided to the senior CCL nurse, who reviews the documentation within 24 to 48 hours. This information is entered, in chronological order, into the Sextant database. Additional information is acquired and entered as the patient moves through the Critical Care and Progressive Care Units. For patients who are transferred to another hospital, that hospital and associated physicians are called to obtain discharge summaries and procedure notes.

According to AAMC, each pPCI patient is visited by a CCL nurse or other staff within 36 hours prior to discharge and is provided with information about follow-up. Additional follow-up contact information is obtained at this time. Follow-up call sheets are generated monthly and reviewed weekly to identify all pPCI patients who are within two weeks of the six-week follow-up date. Calls are placed at the indicated times. In the case of unanswered calls, a message stating the reason for the call and a call back number to be used during non-business hours is left on an answering machine, if available.

AAMC notes that calls also are placed to physician offices and tertiary hospitals in order to gather additional information; the Medical Director may facilitate these contacts. Follow-up data are entered into the Sextant database as they are obtained. Sextant provides a mechanism for double checking that all follow-up information has been obtained and recorded. In December 2007, AAMC began using its recently developed, in-house data repository system to facilitate pPCI patient follow-up tracking, and also assigned more staff to making follow-up calls.

BWMC

According to BWMC, six weeks after the patient's pPCI, a staff member calls the patient during business hours at the telephone number provided at the time of admission. If there is no answer, a message is left stating the reason for the call and information for contacting the hospital. In the absence of a return call within two or three days, the same number is called during the evening, and, if unanswered, a call-back message is left for the patient. If there is no return call, the same number is dialed on a weekend; if no one answers the same message is left.

BWMC indicates that if it is unable to establish contact via the patient-provided telephone number, staff will try alternative numbers, including those of family members identified at the time of admission. The same strategy of sequentially calling during business hours, during the evening, and on weekends is employed. If telephone contact with the patient cannot be established, a letter is sent to the patient's address (if known and accurate) requesting that he or she contact the hospital. BWMC staff also will contact the patient's primary care

physician, asking the physician's practice to advise the patient to contact the hospital and/or to obtain current contact information.

### HCH

HCH states that it begins familiarizing the pPCI patient and the patient's family about the follow-up plan at the time of admission. A designated myocardial infarction follow-up nurse explains the need and purpose of the follow-up process, and obtains/verifies the patient's contact information and similar information for an alternate contact. On discharge, the patient is reminded of the follow-up schedule and plan, and contact information is confirmed. A reminder letter is sent to the patient and family two weeks before the scheduled follow-up day.

According to HCH, for patients transferred to another acute care center, the follow-up nurse verifies the admission to, and discharge from the transfer hospital. Upon discharge, the follow-up nurse will request by facsimile that the transfer hospital provide the patient's chart, angioplasty and/or CABG report, and discharge or death summary (as applicable). Typically, this information is received within two weeks of the request; if not, the Director of Medical Records at the transfer hospital is contacted and asked to facilitate compliance with the request.

HCH indicates that the follow-up nurse calls the patient at the preferred number on the scheduled follow-up day. If contact with the patient is not achieved, the following strategy is implemented: repeated calling on different days (including weekends) and at various times; calling the designated alternate contact; searching online directories for updated contact information for the patient and/or the alternate contact; mailing the follow-up questionnaire to the patient for self-completion and return; calling the patient's cardiologist or other health care providers to confirm office visit(s) and follow-up status; determining if the patient has been readmitted to the hospital or has a scheduled visit; checking the Kaiser Permanente database for office visit information and physician notes; and, finally, checking the Social Security Death Index. If the patient was discharged to a nursing home and the follow-up nurse is unable to get in touch with the alternate contact, the nursing home will be contacted. If patient contact has not been established by any of these measures, the patient is coded as lost to follow-up.

### JHBMC

JHBMC indicates that it attempts to obtain pPCI patient follow-up information between four and six weeks post-procedure. Telephone contact is attempted a minimum of three times on three different occasions. The first occurs between 0900 and 1100 on a weekday, the second between 1100 and 1400 on a weekday, and the third between 1400 and 1700 on a weekday. A letter also is sent to the patient requesting contact with the data coordinators. If telephone contact is not achieved, the patient's cardiologist is contacted to obtain an update on the patient and to determine if there is new contact information. The hospital's patient registry is queried for information about readmissions, visits, or testing. If there is evidence of recent contact, further attempts are made to contact the patient. The Social Security Death Index and local obituary notices are examined for information about the patient. A patient is considered lost to follow-up if these processes fail to establish contact with the patient.

## SGAH

According to the hospital, on discharge, pPCI patients at SGAH complete a series of forms authorizing or consenting to the release of the patient's information, and allowing the hospital to obtain the patient's medical record from other facilities. Another form is used to acquire contact information for the patient, family members or friends, and the patient's primary care physician and cardiologist. The patient also is provided with a follow-up visit schedule. Follow-up calls are placed to the patient within the allotted time frame. If these attempts are unsuccessful, the primary care physician and/or cardiologist will be contacted for updated information about the patient. If contacting these physicians' practices fails to provide useful follow-up or new contact information, calls are placed to the previously identified family members or friends in order to gather follow-up information or updated contact information.

## SMHC

SMHC indicates that the pPCI coordinator attempts to contact each patient by telephone at the prescribed time using the telephone number listed on the pPCI demographic sheet; each number is called at least three times. If necessary, the coordinator leaves a message requesting a return call. The hospital's information system is queried to determine if the patient has been re-admitted, and the patient's physician is called to determine if s/he has returned for follow-up care. The Social Security Death Index may be consulted, but this generally has not proven helpful. Similarly, mailing follow-up requests to patient-designated addresses has been futile.

## SAH

According to SAH, current pPCI patient follow-up procedures are the responsibility of a CCL nurse. The hospital administration recently approved the creation of a new position, Clinical Data Coordinator (CDC), who will oversee all data input and timelines, as well as the CCL secretary and nurse(s) who are involved in data collection and management. The CDC also will monitor and report time-to-treatment to CCL and emergency department staff, and at the monthly interventional and Chest Pain Committee meetings. The CCL secretary captures the initial patient data, sets up data folders, and assigns patient numbers for entry into the Maryland STEMI Registry. The CCL nurse gathers all hospital, procedure, complication, and follow-up data. Initial data are to be entered into the hospital's registry (Sextant) within two weeks of patient discharge/transfer. Six-week follow-up data are to be entered two weeks prior to or after the designated discharge date in accord with registry guidelines. The data team is equipped with three dedicated computers and three scanners to facilitate data entry and management.

As described by SAH, when a pPCI patient arrives at the CCL, the nurse providing care places the initial data, e.g., EKG(s), demographic information, and procedure notes, in a folder that is given to the CCL secretary. The secretary enters the information into electronic forms. The nurse monitors the patient and acquires additional data until the time of discharge/transfer. The CDC will obtain all transfer hospital data, and will work with the nurse to ensure that all post-procedure data are entered into Sextant. The nurse will obtain follow-up data and enter it into the database.

## Analysis and Findings

Each applicant's pPCI patient follow-up rates based on Maryland STEMI Registry data are presented in Table 22. These data were obtained on May 17, 2008 following review by the Registry Director, Thomas Aversano, MD, a cardiac interventionalist. Rates are based on the number of pPCI patients discharged alive.

**Table 22. Percent of pPCI Patients at Applicant Hospitals for Whom Six-week Follow-up Data were Obtained.\***

|       | 2006 |     |     |     |       | 2007 |     |     |     |       | 2-Year<br>Total |
|-------|------|-----|-----|-----|-------|------|-----|-----|-----|-------|-----------------|
|       | 1st  | 2nd | 3rd | 4th | Total | 1st  | 2nd | 3rd | 4th | Total |                 |
| AAMC  | 100  | 83  | 69  | 61  | 78    | 77   | 93  | 100 | 90  | 89    | 84              |
| BWMC  | 100  | 100 | 100 | 100 | 100   | 100  | 100 | 100 | 96  | 99    | 99              |
| HCH   | 100  | 60  | 40  | 50  | 63    | 80   | 50  | 82  | 94  | 84    | 75              |
| JHBMC | 100  | 91  | 89  | 80  | 90    | 94   | 92  | 87  | 100 | 94    | 93              |
| SGAH  | 100  | 95  | 100 | 94  | 97    | 100  | 91  | 95  | 100 | 97    | 97              |
| SMHC  | 100  | 100 | 89  | 73  | 90    | 93   | 92  | 94  | 100 | 94    | 92              |
| SAH   | 100  | 86  | 95  | 96  | 94    | 100  | 100 | 100 | 89  | 97    | 96              |

\* Based on the number of pPCI patients discharged alive

Overall, BWMC and SGAH have been consistently successful in obtaining follow-up for the vast majority of pPCI patients (Table 22), both on an annual and 2-year basis. SAH was the next most successful, followed by JHBMC, SMHC, and AAMC. HCH has been less successful than the other applicants in obtaining follow-up on pPCI patients. COMAR 10.24.05 requires that npPCI research waiver recipients achieve and maintain 98% follow-up rates, and the C-PORT study protocol requires a 100% follow-up rate. Full year follow-up rates based on the preliminary 2007 STEMI Registry data indicate that most applicants will need to improve follow-up practices to meet the State and study requirements. For the most recent full year, 2007, follow-up rates were as follows: BWMC – 99%; SGAH – 97%; SAH – 97%; JHBMC – 94%; SMHC – 94%; AAMC – 89%; and HCH – 84%.

BWMC, SGAH, and SAH are considered likely to be able to achieve the follow-up rates required by COMAR 10.24.05 and the study protocol based on recent performance. JHBMC and SMHC also are likely to meet those requirements if they continue to improve their processes and practices for obtaining follow-up. Recent performance suggests that further improvements in the processes and practices used by AAMC and HCH for obtaining follow-up will be necessary for either hospital to meet the requirements. The Commission notes that it is generally more difficult to obtain follow-up information for patients treated emergently (e.g., pPCI) than from patients enrolled in a study prior to treatment as will be the case for the npPCI study; however, the study requires a longer period of follow-up, increasing the difficulty of achieving a rate that is greater than or equal to 98%.



*(e) An applicant's current performance under its primary PCI waiver.*

Analysis and Findings

The Commission established the Maryland STEMI Registry in 2006 to facilitate monitoring of pPCI services provided by hospitals with Commission-issued waivers, which permitted the hospitals to perform pPCI without on-site cardiac surgery services. Under COMAR 10.24.17, only certain patient groups are eligible to receive pPCI at a waiver hospital. Data for each patient are entered into the Registry, and regularly reviewed by the Registry Director. This review includes examination of the electrocardiogram (ECG) to confirm the STEMI (or new left bundle branch block, LBBB) diagnosis and the elapsed time between patient arrival at the hospital and first use of an interventional device, i.e., the door-to-balloon (DTB) time,<sup>39</sup> which is associated with patient outcome. The medical review may also provide the Commission with information regarding the circumstances of a case (such as whether it was reasonable to take a patient to the lab for cath with a view toward pPCI, for example, ST-elevation of borderline significance, paced rhythm, complete heart block). The Registry provides quarterly and annual reports characterizing these and other performance indicators for each pPCI waiver hospital, as well as summary data for all patients entered into the database. The parameters employed in the Registry reflect each waiver hospital's commitment to the quality of patient care.

The Commission regularly reviews the performance of pPCI waiver hospitals by examining three key parameters. These are: (1) the number and percentage of patients with DTB times of 120 minutes or less (and, conversely, the number and percentage of those with DTB times greater than 120 minutes); (2) the enrollment of appropriate patients, as well as the inappropriate enrollment of patients; and, (3) the volume of pPCI cases. In order to meet the Commission's pPCI waiver requirements,<sup>40</sup> hospitals in the Metropolitan Regional Planning Areas are required to perform at least 49 pPCI procedures annually, and perform pPCI only on patient groups suitable for primary PCI in settings without on-site cardiac surgery. These and related data for the applicant hospitals during 2006 and 2007 are presented in Table 23.

Door-to-balloon time is important because a large body of scientific evidence indicates that shorter DTB times are associated with better clinical outcomes.<sup>41</sup> During 2007, all applicants met the Commission's requirement that 80% of patients receiving pPCI at a waiver hospital must have a DTB time of 120 minutes or less<sup>42</sup>. SGAH and SMHC provided pPCI in

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<sup>39</sup> DTB time is calculated in an alternative manner when a patient arrives with a history of chest pain and whose initial ECG is normal or non-diagnostic. In this case, if the initial ECG is entered into the Registry for review and confirmation along with a second ECG diagnostic of STEMI, then the date and time of the second ECG is used as the door (arrival) time. For already hospitalized patients, the door time is the time of the first recorded ECG indicative of STEMI.

<sup>40</sup> Maryland Health Care Commission, State Health Plan for Facilities and Services: Specialized Health Care Services – Cardiac Surgery and Percutaneous Coronary Intervention Services, COMAR 10.24.17.

<sup>41</sup> See for example, Nallamothu BK et al. Time to treatment in primary percutaneous coronary intervention. *N Eng J Med* 2007;357:1631-1638.

<sup>42</sup> The current pPCI guidelines of the American College of Cardiology/American Heart Association call for a DTB time of 90 minutes. Smith SC et al. 2006. ACC/AHA/SCAI 2005 Guideline update for percutaneous coronary intervention. American College of Cardiology, Washington, DC, and American Heart Association, Dallas TX. 121p. <http://www.acc.org/clinical/guidelines/percutaneous/update/index.pdf>.

120 minutes or less to 95% and 94%, respectively, of the eligible patients. All other applicants performed timely pPCI for between 88% (AAMC) and 83% (SAH) of patients. This is a marked improvement over 2006, when only AAMC and SGAH performed pPCI in accord with the DTB time requirements, with 87% of patients at these hospitals receiving pPCI within 120 minutes of hospital arrival (Table 23).

The median DTB time provides another measure of timely delivery of pPCI services. For each hospital, DTB times were lower in 2007 than in 2006. This means that more procedures are being completed in less time. This improvement results in part from the Commission's strong message to waiver hospitals that they would have to relinquish their pPCI waivers unless the Commission's DTB, volume, and other requirements were met.<sup>43</sup>

The Commission also requires that a waiver hospital perform pPCI on patients who meet the diagnostic criteria for STEMI (or new LBBB). During 2006, four of the seven applicants performed PCI on a total of 12 ineligible patients. The Commission timely notified the responsible hospitals of inappropriate treatment of these patients. Five ineligible patients received PCI during 2007, one by AAMC, and two each by JHBMC and HCH; HCH had enrolled no ineligible patients the previous year. In 2006-2007, SMHC enrolled only one ineligible patient. Over the two-year period, BWMC and SGAH are the only applicants that did not perform PCI on any ineligible patients.

Hospitals, such as the applicants, that are located in the Metropolitan Regional Service Areas must maintain an annual pPCI volume of at least 49 in order to retain a pPCI waiver. During 2006, the number of pPCI procedures ranged from 35 at HCH to 105 at SMHC (Table 23). Looking at the preliminary 2007 annual data, AAMC and SGAH each performed over 90 pPCI procedures and were the two highest volume applicant hospitals. BWMC (67), JHBMC (64), SMHC (73), and SAH (77) had moderate volume pPCI programs in 2007. The closure for renovations of BWMC's sole catheterization lab for ten weeks in 2007 contributed to a decrease in pPCI procedures in 2007. HCH, with 51 pPCI procedures in 2007, also meets the Commission's minimum pPCI volume requirement.

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<sup>43</sup> One waiver hospital that did not meet the Commission's requirements voluntarily closed its pPCI service and another waiver hospital closed its pPCI service after notification from the Commission.

**Table 23. Numbers of Registrants, STEMI Patients, Ineligible Patients, Cardiac Catheterized (Cathed) Patients, and pPCI Procedures in 2006 and 2007 at Applicant Hospitals.\***

| AAMC        | Number of Registrants <sup>A</sup> | Number of STEMI <sup>B</sup> | Number of Ineligible <sup>C</sup> | Number Cathed <sup>D</sup> | Number of pPCI Procedures <sup>E</sup> | Door-to-Balloon Time |               |    |               |    |
|-------------|------------------------------------|------------------------------|-----------------------------------|----------------------------|--|----------------------|---------------|----|---------------|----|
|             |                                    |                              |                                   |                            |  | Median               | < 120 Minutes |    | > 120 Minutes |    |
|             |                                    |                              |                                   |                            |  |                      | Number        | %  | Number        | %  |
| 2006        | 136                                | 132                          | 1                                 | 111                        | 88                                     | 86                   | 77            | 87 | 12            | 13 |
| 2007        | 125                                | 113                          | 1                                 | 114                        | 93                                     | 78.5                 | 83            | 88 | 11            | 12 |
| <b>BWMC</b> |                                    |                              |                                   |                            |  |                      |               |    |               |    |
| 2006        | 124                                | 123                          | 0                                 | 105                        | 82                                     | 99                   | 62            | 76 | 20            | 24 |
| 2007        | 119                                | 119                          | 0                                 | 97                         | 67                                     | 88                   | 58            | 87 | 9             | 13 |
| <b>HCH</b>  |                                    |                              |                                   |                            |  |                      |               |    |               |    |
| 2006        | 58                                 | 58                           | 0                                 | 53                         | 35                                     | 123                  | 17            | 49 | 18            | 51 |
| 2007        | 86                                 | 85                           | 2                                 | 82                         | 51                                     | 95                   | 45            | 85 | 8             | 15 |
| <b>JHMC</b> |                                    |                              |                                   |                            |  |                      |               |    |               |    |
| 2006        | 82                                 | 79                           | 1                                 | 51                         | 39                                     | 122                  | 19            | 49 | 20            | 51 |
| 2007        | 98                                 | 98                           | 2                                 | 87                         | 64                                     | 97.5                 | 57            | 86 | 9             | 14 |
| <b>SGAH</b> |                                    |                              |                                   |                            |  |                      |               |    |               |    |
| 2006        | 113                                | 113                          | 0                                 | 105                        | 92                                     | 97                   | 80            | 87 | 12            | 13 |
| 2007        | 109                                | 109                          | 0                                 | 107                        | 96                                     | 88.5                 | 91            | 95 | 5             | 5  |
| <b>SMHC</b> |                                    |                              |                                   |                            |  |                      |               |    |               |    |
| 2006        | 176                                | 175                          | 1                                 | 158                        | 105                                    | 99                   | 80            | 75 | 26            | 25 |
| 2007        | 103                                | 103                          | 0                                 | 98                         | 73                                     | 86                   | 68            | 94 | 5             | 7  |
| <b>SAH</b>  |                                    |                              |                                   |                            |  |                      |               |    |               |    |
| 2006        | 126                                | 116                          | 9                                 | 105                        | 72                                     | 102                  | 53            | 70 | 23            | 30 |
| 2007        | 105                                | 105                          | 0                                 | 103                        | 77                                     | 83.5                 | 64            | 83 | 13            | 17 |

Source: Maryland Health Care Commission, STEMI Registry: 2006 data, April 17, 2007, and STEMI Registry: preliminary 2007 data, May 17, 2008

\* Door-to-Balloon time is the elapsed time between hospital arrival, based on the ECG, and the time of first device use. The first device used is almost always a balloon-type device, but occasionally is a thrombectomy device.

<sup>A</sup> Registrant – patient entered in the Maryland STEMI Registry

<sup>B</sup> STEMI – patient presenting with ST-segment elevation myocardial infarction

<sup>C</sup> Ineligible – registrant who had non-diagnostic or no ECG and had PCI attempt

<sup>D</sup> Cathed – registrant undergoing diagnostic cardiac catheterization

<sup>E</sup> pPCI procedure – successful advance of guidewire across a coronary lesion, and use of a cardiac angioplasty device (balloon, stent, thrombectomy) on an eligible patient

In summary, while all applicants met the Commission's door-to-balloon requirements in 2007, only AAMC and SGAH met this important quality measure in both 2006 and 2007. These same two hospitals had a high pPCI case volume in 2007. SGAH and BWMC are the only applicants with a consistent record of performing PCI only on appropriate patients under a pPCI waiver.

***COMAR 10.24.05.07 A. Each hospital granted a waiver to perform non-primary PCI within the C-PORT study shall provide data to the Commission in a form and manner acceptable to the Commission.***

The letter that each applicant received from the C-PORT E Principal Investigator outlining the commitments required of the hospital in order to participate in the study stated that “The hospital authorizes the C-PORT Principal Investigator to provide data to the Commission about patients enrolled in the study by the applicant hospital.”

#### Analysis and Findings

The president and/or CEO of each applicant hospital signed the C-PORT E letter acknowledging the hospital’s receipt and acceptance of the requirements that the hospital and staff would be expected to meet in order to participate in the study.

#### ***Additional Information***

The eligibility of hospitals without on-site cardiac surgical backup in the Metropolitan Baltimore and Metropolitan Washington Regional Service Areas to apply for an npPCI research waiver is established, in part, by possession of a two-year waiver to provide pPCI to patients with ST-segment elevation myocardial infarction (STEMI). Under the pPCI waiver program (COMAR 10.24.17), hospitals are required to provide pPCI services 24 hours a day, seven days a week, 365 days a year. As part of the npPCI research waiver application, applicant hospitals were required to report all incidents when the cardiac catheterization laboratory was unavailable for patient treatment (down time) and changes to CCL equipment since this information was last reported during spring 2007. In addition, the hospitals were required to submit a signed affidavit attesting to the veracity of the information provided, agreeing to provide additional information as requested, and acknowledging the conditions under which a hospital may be required to relinquish an npPCI research waiver.

#### Analysis and Findings

Table 24 summarizes the incidence and cumulative duration of equipment- and staff-related down time at each applicant hospital. In general, there were few instances when the cardiac catheterization laboratories at each hospital were unavailable for use. In most cases, facility down time was associated with routine equipment maintenance or service, and was generally of limited duration. SAH closed both CCLs on two weekends as part of a hospital renovation project. Both AAMC and HCH reported one instance when the CCLs were unavailable because of insufficient staff. Although none of the reported closures are known to have affected patient care, this parameter warrants continued scrutiny because of the added demands placed on equipment and staff as the volume of PCI procedures increases at hospitals receiving an npPCI research waiver.

**Table 24. Incidence and Cumulative Duration (Hours) of Equipment- and Staff-Related Down Time at Each Applicant Hospital Since it Applied to Renew its pPCI Waiver.\***

| Hospital          | Laboratory 1      |                        |               |          | Laboratory 2      |          |               |          |
|-------------------|-------------------|------------------------|---------------|----------|-------------------|----------|---------------|----------|
|                   | Equipment-related |                        | Staff-related |          | Equipment-related |          | Staff-related |          |
|                   | Number            | Duration               | Number        | Duration | Number            | Duration | Number        | Duration |
| AAMC              | 2                 | 21.15                  | 1             | 54       | 2                 | 16.47    | 1             | 54       |
| BWMC              | 1                 | 1728 (48) <sup>A</sup> | 0             | -        | NA <sup>B</sup>   | NA       | NA            | NA       |
| HCH               | 3                 | 7                      | 1             | 36       | 3                 | 7        | 1             | 36       |
| JHBMC             | 4 <sup>C</sup>    | 20                     | 0             | -        | 0                 | -        | 0             | -        |
| SGAH <sup>D</sup> | 6                 | 25.5                   | 0             | -        | 5                 | 21       | 0             | -        |
| SMHC              | 9                 | 26.7                   | 0             | -        | 19                | 45.5     | 0             | -        |
| SAH               | 4 <sup>D</sup>    | 133                    | 0             | -        | 6 <sup>E</sup>    | 139      | 0             | -        |

\* Renewal Applications from Hospitals in the Metropolitan Baltimore Regional Service Area were Due on April 18, 2007. Those From Hospitals in the Metropolitan Washington Regional Service Area Were Due on May 16, 2007.

<sup>A</sup> The BWMC CCL was closed 1680 hours (March 6 through May 14, 2007) for total replacement. Number in parentheses is the number of hours the CCL was unavailable excluding the renovation work.

<sup>B</sup> Not applicable, BWMC has only one cardiac catheterization laboratory

<sup>C</sup> JHBMC plans to replace existing radiology in this room with a new imaging system prior to July 1, 2008. During renovation all diagnostic cardiac catheterizations and pPCI procedures will be performed in the hospital's second CCL.

<sup>D</sup> Laboratory 1 corresponds to hospital Lab B and Laboratory 2 corresponds to hospital Lab C

<sup>E</sup> Both rooms were out-of-service on each of two weekends (62.5 hours/lab/ weekend) to accommodate ground floor renovations to the hospital.

Each of the applicant hospitals submitted information on the installation, removal, and/or upgrading of equipment in the cardiac catheterization laboratory that is essential to performing PCI procedures. Essential equipment includes X-ray machines, hemodynamic system, thrombectomy system, injector, defibrillator, balloon pump, IVUS, and laser. Table 25 identifies essential equipment changes and upgrades at each applicant hospital since this information was last reported during spring 2007.

BWMC and SAH upgraded key components of the existing CCL facilities at each respective hospital. HCH and JHBMC replaced specific parts integral to cardiac imaging and other aspects of CCL operation. AAMC, SGAH, and SMHC did not report any equipment changes and/or upgrades in the months preceding submission of the npPCI research waiver applications. The reported changes suggest that the hospitals are timely identifying and implementing changes appropriate to providing reliable services using advanced technology.

**Table 25. Changes and/or Upgrades of Cardiac Catheterization Laboratory Equipment at Each Applicant Hospital Since it Applied to Renew its pPCI Waiver.\***

| <b>Hospital</b>         | <b>Laboratory 1</b>  | <b>Laboratory 2</b>  |
|-------------------------|--|--|
| <b>AAMC<sup>A</sup></b> | No changes   | No changes   |
| <b>BWMC</b>             | CCL remodeled & equipment replaced (3/6/07 – 5/14/07); IABP replaced & upgraded (10/9/07)                                    | NA <sup>B</sup>  |
| <b>HCH<sup>B</sup></b>  | Injector replaced (7/07)   | No changes   |
| <b>JHBMC</b>            | Replaced radiologic imaging pick-up tube (10/15/07, 10/25/07, 11/3/07)   | No changes   |
| <b>SGAH</b>             | No changes   | No changes   |
| <b>SMHC</b>             | No changes   | No changes   |
| <b>SAH</b>              | Digital imaging, archiving, retrieval & electronic documentation system upgraded (9/15/07); defibrillator upgraded (1/15/08) | Digital imaging, archiving, retrieval & electronic documentation system upgraded (9/15/07); defibrillator upgraded (1/15/08) |

\* Renewal applications from hospitals in the Metropolitan Baltimore Regional Service Area were due on April 18, 2007. Those from hospitals in the Metropolitan Washington Regional Service Area were due on May 16, 2007.

<sup>A</sup> On August 5, 2008, AAMC reported that, subsequent to filing its application, the hospital performed an upgrade to Cardiac Catheterization Lab 4; the upgrade was started on May 19 and completed on July 7. According to AAMC, rooms 5 and 2 were available for procedures and the hospital experienced no disruption of service.

<sup>B</sup> Not applicable, BWMC has only one cardiac catheterization laboratory

<sup>C</sup> HCH needed to rent an IABP on three occasions during 2007 because the hospital's single IABP was in use. If the hospital receives a waiver to participate in the C-PORT study, HCH will purchase a second IABP.

Each applicant submitted an affidavit stating that the information provided in the application was true and correct; agreeing to provide timely, accurate, and complete data as specified by the Commission; and acknowledging the conditions under which a hospital receiving an npPCI research waiver is required to relinquish the waiver.

## SUMMARY AND RECOMMENDATION

The Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) study of the safety and effectiveness of elective angioplasty (C-PORT E study) affords an opportunity for Maryland hospitals to participate in a study whose outcome may inform future health care policy planning in the State. COMAR 10.24.05 established a one-time, two-phase application process for the Commission to identify up to six hospitals without on-site cardiac surgery to participate in the C-PORT E study. The first phase provides for the comparative review of applications from qualified hospitals in the Metropolitan Baltimore and Metropolitan Washington Regional Service Areas. Seven hospitals applied for research waivers during this first phase. Applications were received from Anne Arundel Medical Center (AAMC), Baltimore Washington Medical Center (BPMC), Johns Hopkins Bayview Medical Center (JHBMC), and St. Agnes Hospital (SAH) in the Metropolitan Baltimore Regional Service Area, and Holy Cross Hospital (HCH), Shady Grove Adventist Hospital (SGAH), and Southern Maryland Hospital Center (SMHC) in the Metropolitan Washington Regional Service Area. The second phase, with applications due in October 2008, permits qualified hospitals in rural areas to apply for an npPCI research waiver and reflects the importance to the overall study of obtaining data from hospitals in non-metropolitan areas.<sup>44</sup>

COMAR 10.24.05.04A(2) establishes review criteria for the evaluation of applications from hospitals seeking a waiver to perform npPCI procedures as part of the C-PORT E study. Each applicant must meet these requirements in order to be considered for an npPCI waiver. Table 26 summarizes the analysis and findings for each of the review criteria. In addition, COMAR 10.24.05.04A(3) provides that the Commission shall consider other matters, including five specific factors, in determining whether to grant waiver applications. These additional factors, summarized in Table 27, are intended to be used to distinguish among applicants that meet the requirements of Regulation .04A(2) in deciding which of the qualified applicants should be granted npPCI waivers.

It is important to note that the criteria for waiver approval to participate in the Atlantic C-PORT E research study are designed to select sites most able to contribute to a successful conclusion of the 2-year research project. The Commission has emphasized that waivers to participate in the research study are strictly limited to the research participation. No patients may receive non-primary angioplasty at these sites unless they are enrolled in the research study and randomized to receive angioplasty at the waiver hospital. Unless extended by a vote of the Commission, each research waiver expires at the earliest of the following: 2 years from the date on which the waiver was first issued; the date patient accrual into the C-PORT E study ends; when the Commission finds that the study is not accruing patients at an acceptable rate; or when the Commission finds that the study is unlikely to produce reliable results to guide public policy. The results of this study will inform subsequent revisions of the State Health Plan. If, based on

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<sup>44</sup> While this second phase of the review provided the opportunity for hospitals in both Western Maryland and the Eastern Shore to apply, only hospitals in Western Maryland (Frederick Memorial Hospital and Washington County Hospital) are expected to qualify to submit letters of intent to file an application. According to the schedule published by the Commission, letters of intent in the second phase of the review are due September 17, 2008.

the evidence from this and other studies, a later revision of the State Health Plan were to recommend issuance of waivers or certificates of need allowing the performance of non-primary angioplasty without cardiac surgery on-site, the criteria applied in that review would be different than the criteria used to identify participants in a research study.

### **Executive Director's Recommendation**

The Commission's regulations provide for up to six waiver recipients. The Commission's regulations also provide for a separate phase of this review focused on applicants from Western Maryland.

The Commission adopts the Executive Director's Recommendation that the Commission grant all six waivers by the following process:

- Grant npPCI research waivers to four applicants: Anne Arundel Medical Center, Shady Grove Adventist Hospital, Southern Maryland Hospital Center, and St. Agnes Hospital.
- Hold two waivers in abeyance pending the completion of the review of applications from the Western Maryland Regional Service Area.
- At this time, take no action on the applications filed by Baltimore Washington Medical Center, Holy Cross Hospital, and Johns Hopkins Bayview Medical Center. If the remaining two waivers available under the regulations are not awarded in the review of applications from Western Maryland, Commission staff will look again at the procedure volumes of Baltimore Washington Medical Center, Holy Cross Hospital, and Johns Hopkins Bayview Medical Center, and make additional recommendations so that all six research waivers are awarded.

To warrant consideration for a research project waiver, a hospital must first meet all requirements in Regulation .04A(1)-(2) and, second, should offer advantages in comparison with the other applicants when the additional factors are considered. Based on my review and analysis of the waiver applications, AAMC, SGAH, SMHC, and SAH all meet the required considerations (Refer to Table 26) and, on balance, have strengths, as compared with the other applicants, when the additional factors (Refer to Table 27) specified under COMAR 10.24.05 are considered.

The ability of an applicant for an npPCI waiver to perform least 200 PCIs in the second year of the project is a key requirement for several reasons. First, the ability of a hospital to serve as a site for this research project is highly dependent on the volume of npPCI cases that the hospital will enroll over the course of the study. Second, because this is a time-limited study, required volumes must be achieved quickly (i.e., by Year 2 of the waiver). Based on the study design and experience to date with enrolled hospitals, it is possible that the research study will achieve enrollment targets and be concluded by late 2010. Given this timeframe, it is important to select waiver participants that have institutional resources readily available and a strong referral base likely to generate required volumes without an extended ramp-up period.



Analysis of data on the projected number of potential research participants documented by each waiver applicant shows that AAMC, SGAH, SMHC, and SAH ranked highest among the applicants. Each of these four hospitals is expected to meet or exceed the required 200 npPCI cases [10.24.05.04A(2)(c)]. These four hospitals were also able to exceed the minimum pPCI volume requirement and achieve high or moderate volumes under their pPCI waivers [10.24.05.04A(3)(e)]. AAMC, SGAH, SMHC, and SAH have institutional resources readily available, including two cardiac catheterization laboratories equipped for PCI procedures.

Evidence that a hospital has experience participating in multi-center studies with patient randomization to treatment is considered one indicator of an applicant's ability to successfully participate in the C-PORT E study, particularly at the early outset of the study. While SMHC does not have experience to date in these types of studies, I find that this must be balanced with the fact that it, like the other applicants, has made a commitment to provide the resources necessary for this research study.<sup>45</sup> A hospital's ability to enroll a greater volume of patients into the study is more important to the success of the C-PORT E study than a hospital's history of conducting research or the existence of formal research structure at a hospital.

Minority access is also among the additional factors considered in my review. The racial and ethnic composition of the applicant hospitals' primary and extended service areas and the demographic composition of the cardiovascular inpatient population were analyzed as a measure of the likelihood of recruiting minority participants in the research, thereby resulting in more representative study populations and, thus, more useful generalization of the results across racial and ethnic groups. For three of the four recommended hospitals (SMHC, 75.8%; SAH, 58.3%; and SGAH, 46.3%), the proportion of minorities in their combined PSA/ESA is above the statewide average. The distribution of cardiovascular inpatients served by these three hospitals is relatively consistent with their service area population. While AAMC's service area population has a lower proportion of minorities, as compared to SGAH, SMHC and SAH, the hospital serves minorities among its cardiovascular inpatients in a proportion fairly consistent with its service area population.

The proportion of self-pay/charity/Medicaid as payer sources for inpatients with cardiovascular diagnoses was used as a measure of the uninsured (including low income uninsured) and low-income persons covered by public insurance who were actually served by the hospital. This measure is used as an indication of the commitment of the program to increase access to PCI to individuals traditionally regarded as medically underserved. With respect to the percent of patients with self-pay, charity/Medicaid as payer sources for inpatients with cardiovascular diagnoses, all applicant hospitals, with the exception of JHBMC, were below the statewide average. AAMC, SGAH, SMHC, and SAH ranked 6<sup>th</sup>, 5<sup>th</sup>, 4<sup>th</sup>, and 2<sup>nd</sup> among all waiver applicants based on this measure.

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<sup>45</sup> Each applicant has signed a letter of agreement with the C-PORT Principal Investigator that includes a commitment of resources necessary to comply with the study requirements related to data collection and follow-up: minimum of 1.5 FTEs devoted to the medical data requirements; medical data coordinator must be an RN; responsibilities cannot be added on to an existing position; two clinical data collection personnel must be trained to collect, enter, and transmit clinical data; a billing coordinator to generate, obtain, and enter uniform billing data; and two billing coordinators must be trained [10.24.05.04A(3)(c)].

While the research waiver is time-limited and not intended to consider locations for non-primary angioplasty programs without cardiac surgery on-site beyond the study period, the additional factors include consideration of improvements in the geographic distribution of cardiovascular services. Participation in a clinical trial may be associated with improvements in the use of guideline-recommended care in outpatient settings before and after an acute coronary event. AAMC stated that the hospital has five imaging sites in Annapolis and surrounding areas. Through its Vascular Screening Program, the hospital offers free screening in Annapolis and Bowie, and will offer the service in Queen Anne's County at its Kent Island outpatient medical facility, which opened in April 2008; similar services are being planned for Odenton (Anne Arundel County) and Calvert County. SGAH cited the hospital's Emergency Center, established in August 2006 and located in upper Montgomery County, as improving access to diagnostic tools and screening strategies for risk stratification of patients with symptoms of cardiac disease, to avoid missing patients with myocardial infarction or unstable angina. SMHC reported that the hospital has established community family practice centers in four locations: Waldorf (Charles County), and Fort Washington, Upper Marlboro, and Clinton (Prince George's County). These centers can help promote greater access to cardiovascular services related to health promotion and disease prevention, primary care, and secondary prevention services. Located in southwest Baltimore City, SAH noted that the hospital's campus is one of the locations of the Baltimore Medical System, whose health services include seven primary care health centers that are federally qualified community health centers and, as such, enhance the provision of services for underserved, underinsured and uninsured patients.

Two (AAMC and SMHC) of the four recommended research sites would improve the distribution of cardiovascular services, as measured by distance to existing OHS programs. There would be some improvement in geographic distribution of existing services with the location of a research waiver program at SGAH. On the other hand, SAH is not expected to improve the geographic distribution of cardiovascular services with respect to distance to existing OHS programs.

**Table 26**  
**Summary of COMAR 10.24.05 Requirements**

| Waiver Requirements  | AAMC                 | BWMC                         | HCH                          | JHBMC                        | SGAH                 | SMHC                 | SAH                  |
|--|----------------------|------------------------------|------------------------------|------------------------------|----------------------|----------------------|----------------------|
| <b>•C-PORT E Study</b>   |                      |                              |                              |                              |                      |                      |                      |
| Study Site Inclusion Criteria<br>10.24.05.04A(1)                   | Meets<br>Requirement | Meets<br>Requirement         | Meets<br>Requirement         | Meets<br>Requirement         | Meets<br>Requirement | Meets<br>Requirement | Meets<br>Requirement |
| <b>•Institutional Resources</b>                                    |                      |                              |                              |                              |                      |                      |                      |
| Patient Prioritization Plan<br>10.24.05.04A(2)(a)(i)               | Meets<br>Requirement | Meets<br>Requirement         | Meets<br>Requirement         | Meets<br>Requirement         | Meets<br>Requirement | Meets<br>Requirement | Meets<br>Requirement |
| Written Agreement w/ Tertiary Center<br>10.24.05.04A(2)(a)(ii)     | Meets<br>Requirement | Meets<br>Requirement         | Meets<br>Requirement         | Meets<br>Requirement         | Meets<br>Requirement | Meets<br>Requirement | Meets<br>Requirement |
| Air or Ground Within 30 Minutes<br>10.24.05.04A(2)(a)(iii)         | Meets<br>Requirement | Meets<br>Requirement         | Meets<br>Requirement         | Meets<br>Requirement         | Meets<br>Requirement | Meets<br>Requirement | Meets<br>Requirement |
| <b>•Physician Resources</b>  |                      |                              |                              |                              |                      |                      |                      |
| Minimum of 3 Interventional<br>Cardiologists 10.24.05.04A(2)(b)    | Meets<br>Requirement | Meets<br>Requirement         | Meets<br>Requirement         | Meets<br>Requirement         | Meets<br>Requirement | Meets<br>Requirement | Meets<br>Requirement |
| Physician Criteria<br>10.24.05.04A(2)(b)(i)                        | Meets<br>Requirement | Meets<br>Requirement         | Meets<br>Requirement         | Meets<br>Requirement         | Meets<br>Requirement | Meets<br>Requirement | Meets<br>Requirement |
| Physicians On-Site Within 30 Min-On<br>Call 10.24.05.04A(2)(b)(ii) | Meets<br>Requirement | Meets<br>Requirement         | Meets<br>Requirement         | Meets<br>Requirement         | Meets<br>Requirement | Meets<br>Requirement | Meets<br>Requirement |
| Device Selection Criteria<br>10.24.05.04A(2)(b)(iii)               | Meets<br>Requirement | Meets<br>Requirement         | Meets<br>Requirement         | Meets<br>Requirement         | Meets<br>Requirement | Meets<br>Requirement | Meets<br>Requirement |
| <b>•Minimum Volumes</b>  |                      |                              |                              |                              |                      |                      |                      |
| Minimum Volume 100 Year 1<br>10.24.05.04A(2)(c)                    | Meets<br>Requirement | Meets<br>Requirement         | Meets<br>Requirement         | Meets<br>Requirement         | Meets<br>Requirement | Meets<br>Requirement | Meets<br>Requirement |
| Minimum Volume 200 Year 2<br>10.24.05.04A(2)(c)                    | Meets<br>Requirement | Does Not Meet<br>Requirement | Does Not Meet<br>Requirement | Does Not Meet<br>Requirement | Meets<br>Requirement | Meets<br>Requirement | Meets<br>Requirement |
| <b>•Patient Follow-up</b>  |                      |                              |                              |                              |                      |                      |                      |
| 98% Follow-Up Commitment<br>10.24.05.04A(2)(d)                     | Meets<br>Requirement | Meets<br>Requirement         | Meets<br>Requirement         | Meets<br>Requirement         | Meets<br>Requirement | Meets<br>Requirement | Meets<br>Requirement |

**Table 27**  
**Summary of COMAR 10.24.05 Additional Factors Considered**

| Additional Factors Considered  | AAMC   | BWMC   | HCH  | JHBMC  | SGAH   | SMHC   | SAH  |
|--|--|--|--|--|--|--|--|
| Potential to Improve Geographic Distribution of Cardiovascular Services 10.24.05.04A(3)(a) (NOTE 1)  | Improves Geographic Distribution             | Some Improvement in Geographic Distribution  | No Improvement in Geographic Distribution    | No Improvement in Geographic Distribution    | Some Improvement Geographic Distribution     | Improves Geographic Distribution             | No Improvement in Geographic Distribution    |
| Potential to Increase Access to PCI Services<br>10.24.05.04A(3)(b) (NOTE 2) <ul style="list-style-type: none"> <li>Proportion Service Area Minority Population</li> <li>Ratio Cardiovascular Minority Inpatients : Service Area Minority Population</li> <li>Rank Among Applicants in Proportion Medicaid, Self Pay, Charity Care Cardiovascular Inpatients</li> </ul> | Below Statewide Average<br><br>0.86<br><br>6 | Below Statewide Average<br><br>0.67<br><br>7 | Above Statewide Average<br><br>0.81<br><br>3 | Above Statewide Average<br><br>0.46<br><br>1 | Above Statewide Average<br><br>0.82<br><br>5 | Above Statewide Average<br><br>0.99<br><br>4 | Above Statewide Average<br><br>0.75<br><br>2 |
| Ability and Commitment to Serve as Research Site<br>10.24.05.04A(3)(c) <ul style="list-style-type: none"> <li>Experience in Multi-center/Randomization Study Designs</li> <li>Commitment to Serve as Research Site</li> </ul>  | Yes<br><br>Meets Requirement                 | Yes<br><br>Meets Requirement                 | Yes<br><br>Meets Requirement                 | Yes<br><br>Meets Requirement                 | Yes<br><br>Meets Requirement                 | No<br><br>Meets Requirement                  | Yes<br><br>Meets Requirement                 |

| Additional Factors Considered  | AAMC  | BWMC   | HCH   | JHBMC  | SGAH  | SMHC   | SAH  |
|--|---|--|---|--|---|--|--|
| Demonstration of Successful and Timely Acquisition of Follow-up Data on pPCI Patients<br>10.24.05.04A(3)(d)  | Improvement Needed with Follow-up Data  | Consistent Record with Follow-up Data  | Improvement Needed with Follow-up Data  | Improvement Shown with Follow-up Data 2006-2007                                  | Consistent Record with Follow-up Data   | Improvement Shown with Follow-up Data 2006-2007                        | Consistent Record with Follow-up Data  |
| Current Performance Under pPCI Waiver (2006-2007)<br>10.24.05.04A(3)(e) <ul style="list-style-type: none"> <li>80% of Patients Treated <math>\leq</math> 120 Minutes Door-to-Balloon Time</li> <li>Enrollment of Appropriate Patients (2006-2007)</li> <li>Volume of pPCI Cases (2007) (NOTE 3)</li> </ul> | Met DTB Times in 2006-2007<br><br>More than One NSTEMI Patient<br><br>High Volume | Met DTB Times in 2007<br><br>Consistent Record of Not Performing PCI on NSTEMI Patients<br><br>Moderate Volume | Met DTB Times in 2007<br><br>More than One NSTEMI Patient<br><br>Minimum Volume | Met DTB Times in 2007<br><br>More than One NSTEMI Patient<br><br>Moderate Volume | Met DTB Times in 2006-2007<br><br>Consistent Record of Not Performing PCI on NSTEMI Patients<br><br>High Volume | Met DTB Times in 2007<br><br>One NSTEMI Patient<br><br>Moderate Volume | Met DTB Times in 2007<br><br>More than One NSTEMI Patient<br><br>Moderate Volume |

**NOTE 1:** “Improves Geographic Distribution” means that no npPCI programs are within 10 miles of the applicant; “Some Improvement in Geographic Distribution” means that no npPCI programs are within 5 miles of the applicant; “No Improvement in Geographic Distribution” means that there are 2 or more npPCI programs within 5 miles of the applicant. These figures do not include npPCI programs at hospitals that do not meet the Commission’s minimum volume requirements for a cardiac surgery program.

**NOTE 2:** The “Proportion Service Area Minority Population” reflects the percent of the total population in the combined Primary and Extended Service Areas of the Hospital that is minority (including African American, American Indian, Hawaiian/Pacific Islander, and Hispanic) as compared to the statewide average as of July 1, 2007. The “Ratio Cardiovascular Minority Inpatients : Service Area Minority Population” shows the number of minority inpatients with cardiovascular diagnoses served by the hospital in relation to the demographic composition of the hospital’s service area population. A ratio closer to 1.0 indicates that the composition of the inpatient population is consistent with the service area population.

**NOTE 3:** The volume of pPCI cases reflects data reported to the Commission’s STEMI Registry for calendar year 2007. For the metropolitan regional service areas, high volume is defined as performing more than 87 cases; moderate volume is defined as performing 62-86 cases; and, minimum volume is defined as performing 49-61 cases.

Collectively, these hospitals, two located in the Metropolitan Washington Regional Service Area and two located in the Metropolitan Baltimore Regional Service Area, are most likely to contribute to the success of this study that ultimately will inform statewide policy.

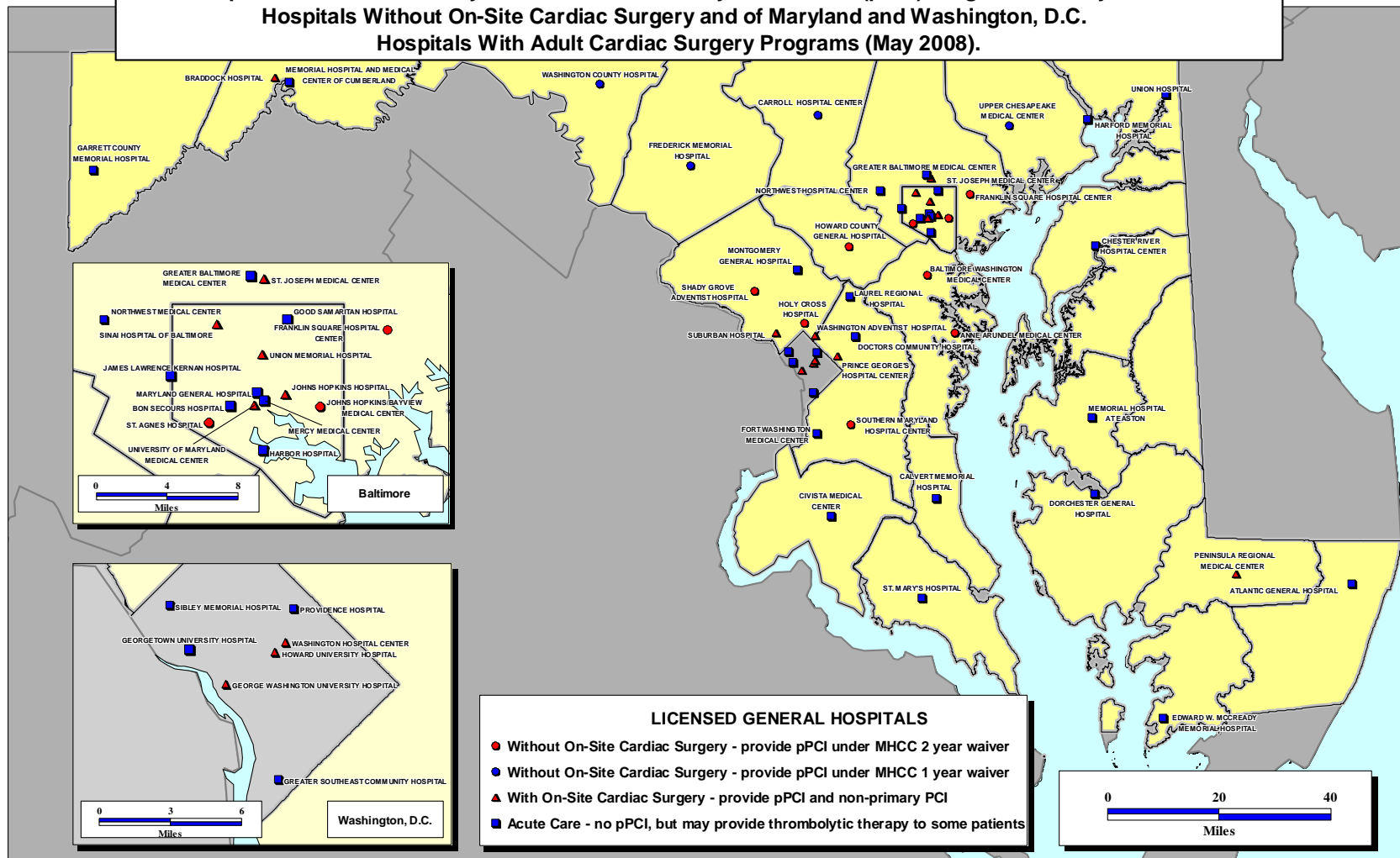
For the reasons outlined in this report, the Commission adopts the Executive Director's Recommendation that the Commission grant all six waivers by the following process:

- Grant npPCI research waivers to four applicants: Anne Arundel Medical Center, Shady Grove Adventist Hospital, Southern Maryland Hospital Center, and St. Agnes Hospital.
- Hold two waivers in abeyance pending the completion of the review of applications from the Western Maryland Regional Service Area.
- At this time, take no action on the applications filed by Baltimore Washington Medical Center, Holy Cross Hospital, and Johns Hopkins Bayview Medical Center. If the remaining two waivers available under the regulations are not awarded in the review of applications from Western Maryland, Commission staff will look again at the procedure volumes of Baltimore Washington Medical Center, Holy Cross Hospital, and Johns Hopkins Bayview Medical Center, and make additional recommendations so that all six research waivers are awarded.

## **Appendix**

### **Maps 1-8**

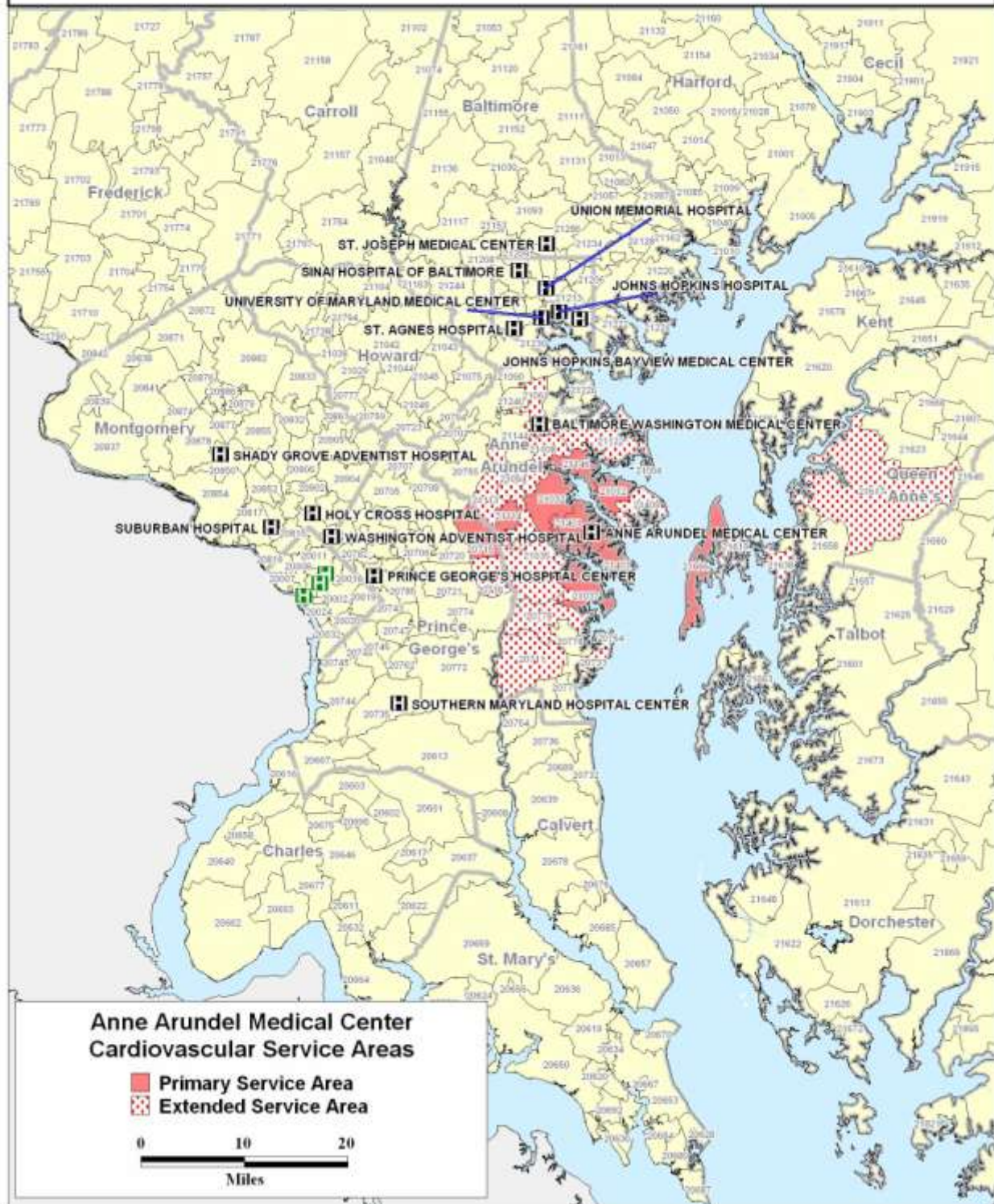
**Map 1. Locations of Primary Percutaneous Coronary Intervention (pPCI) Programs at Maryland Hospitals Without On-Site Cardiac Surgery and of Maryland and Washington, D.C. Hospitals With Adult Cardiac Surgery Programs (May 2008).**



Source: Maryland Health Care Commission (MHCC), May 2008



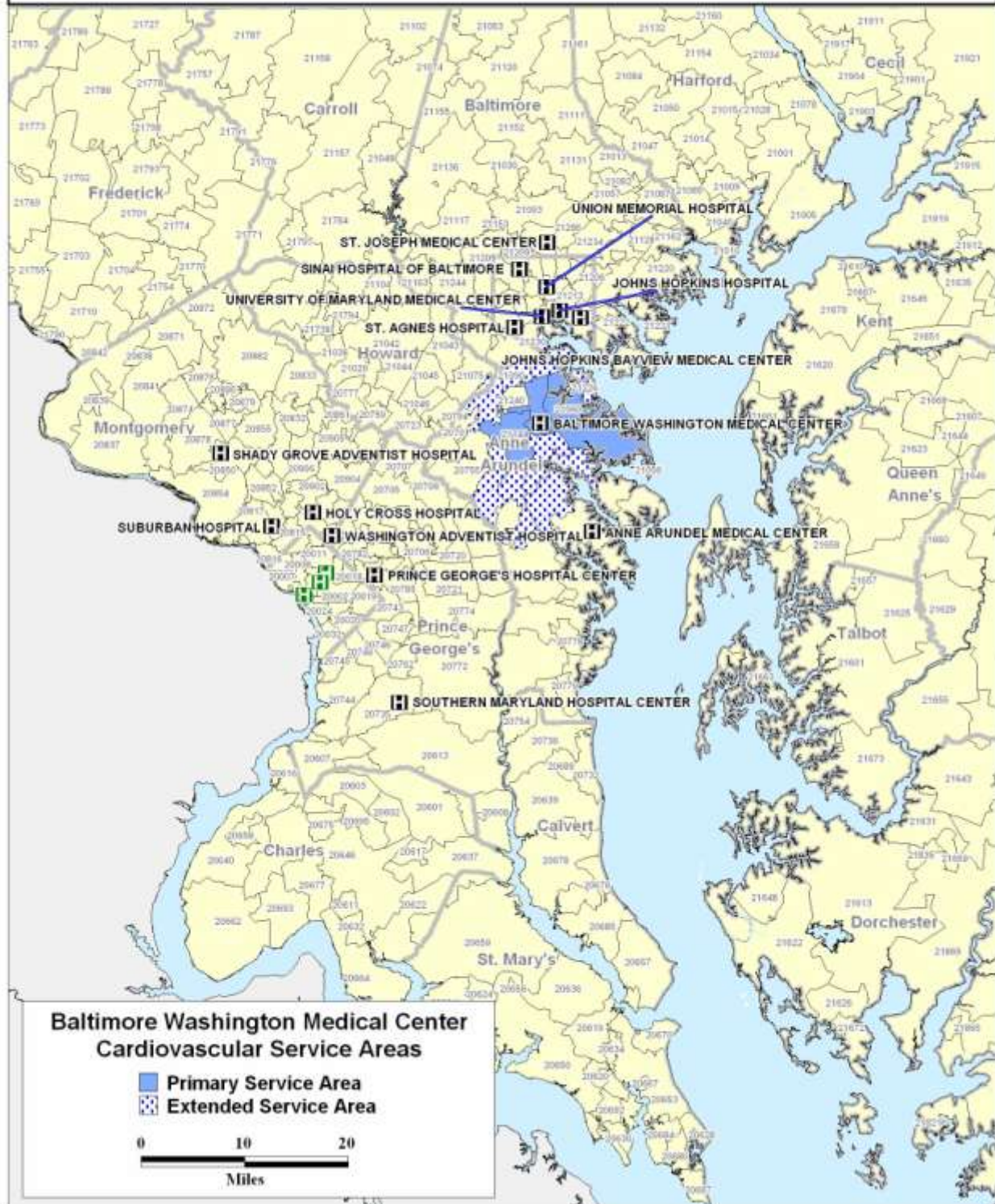
**Map 2. Primary and Extended Service Areas of Anne Arundel Medical Center Based on Calendar Year 2006 Cardiovascular Inpatient Discharges.**



Source: Spatial Insights, Inc., Bethesda, MD



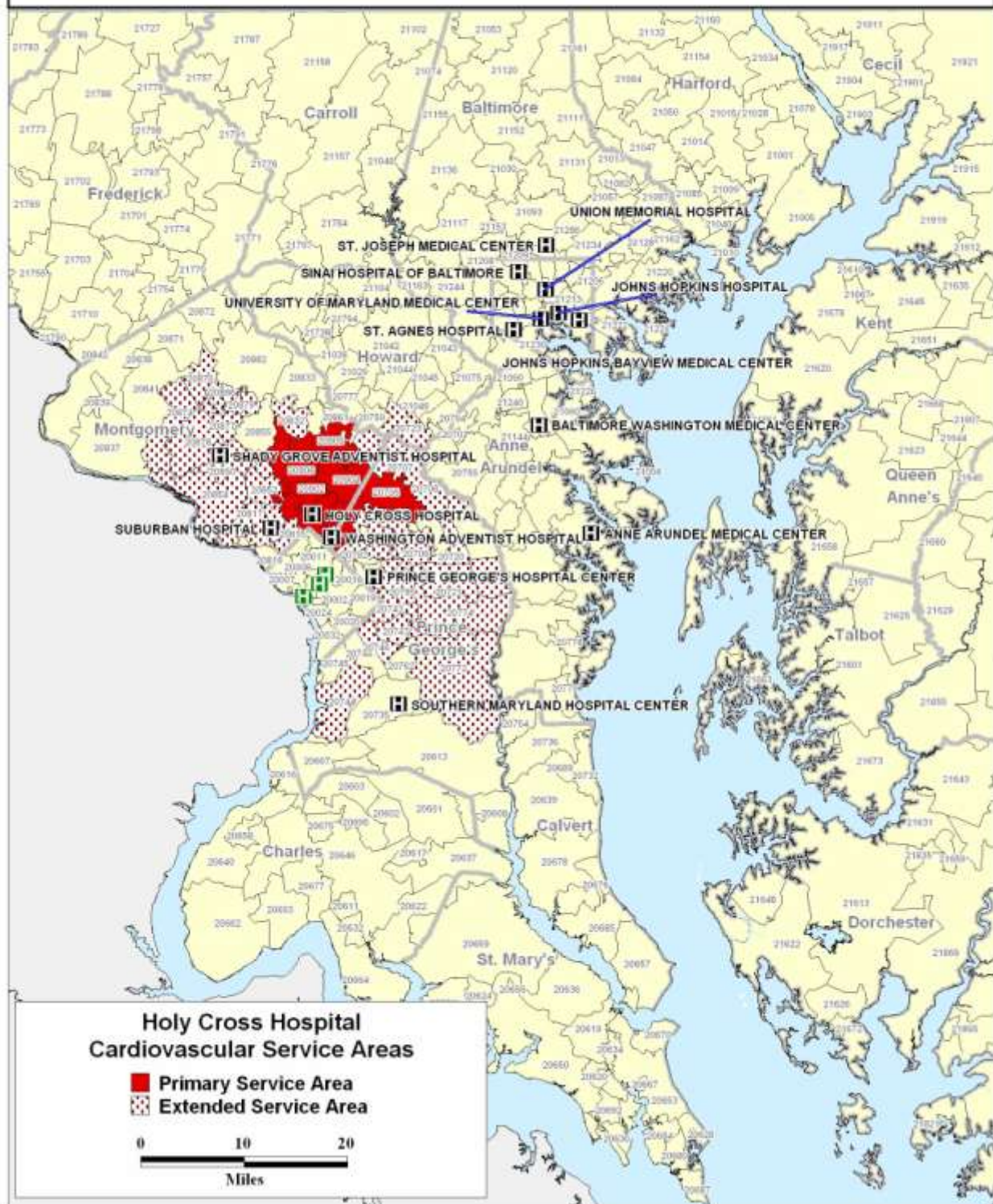
**Map 3. Primary and Extended Service Areas of Baltimore Washington Medical Center Based on Calendar Year 2006 Cardiovascular Inpatient Discharges.**



Source: Spatial Insights, Inc., Bethesda, MD



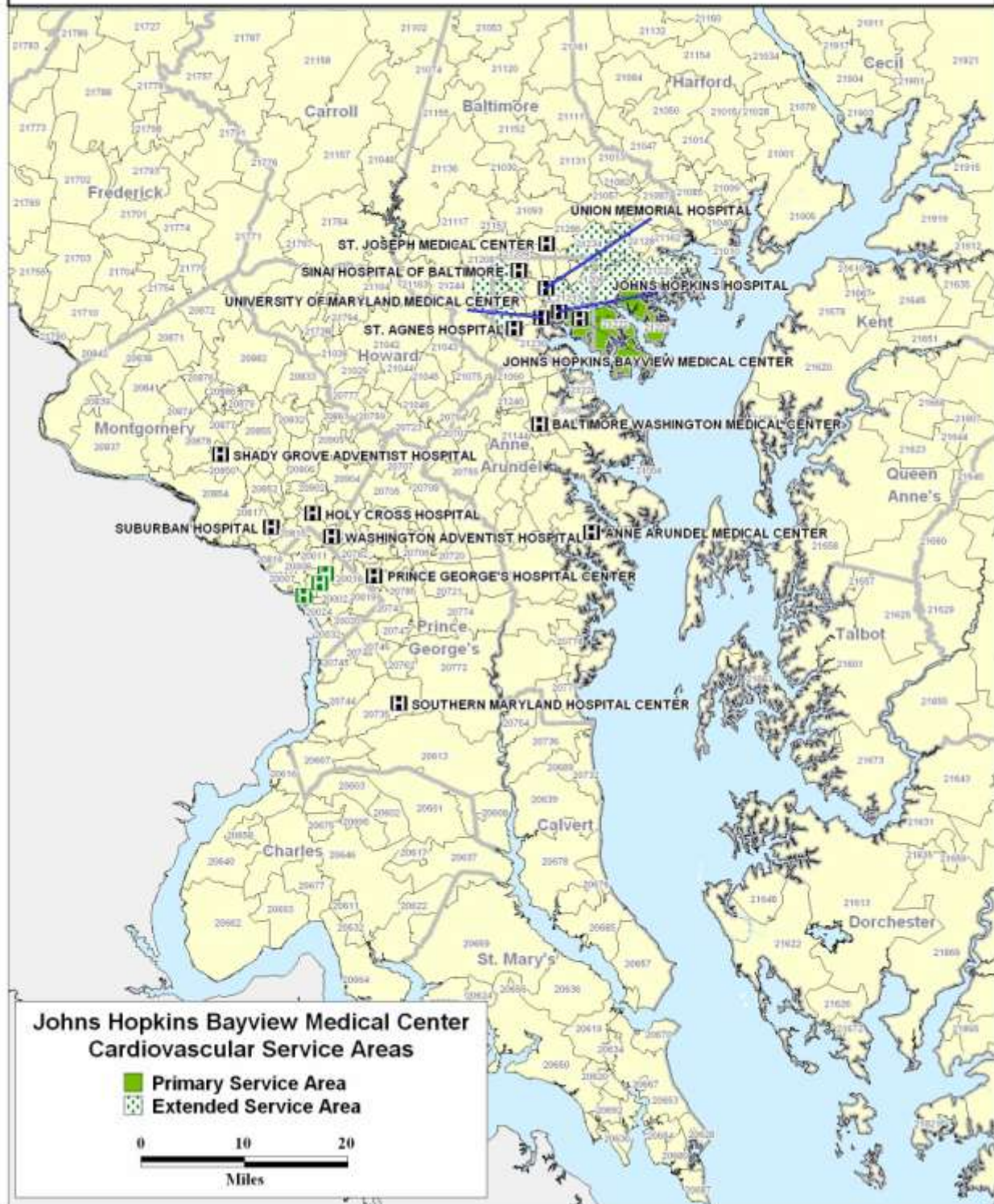
**Map 4. Primary and Extended Service Areas of Holy Cross Hospital Based on Calendar Year 2006 Cardiovascular Inpatient Discharges.**



Source: Spatial Insights, Inc., Bethesda, MD



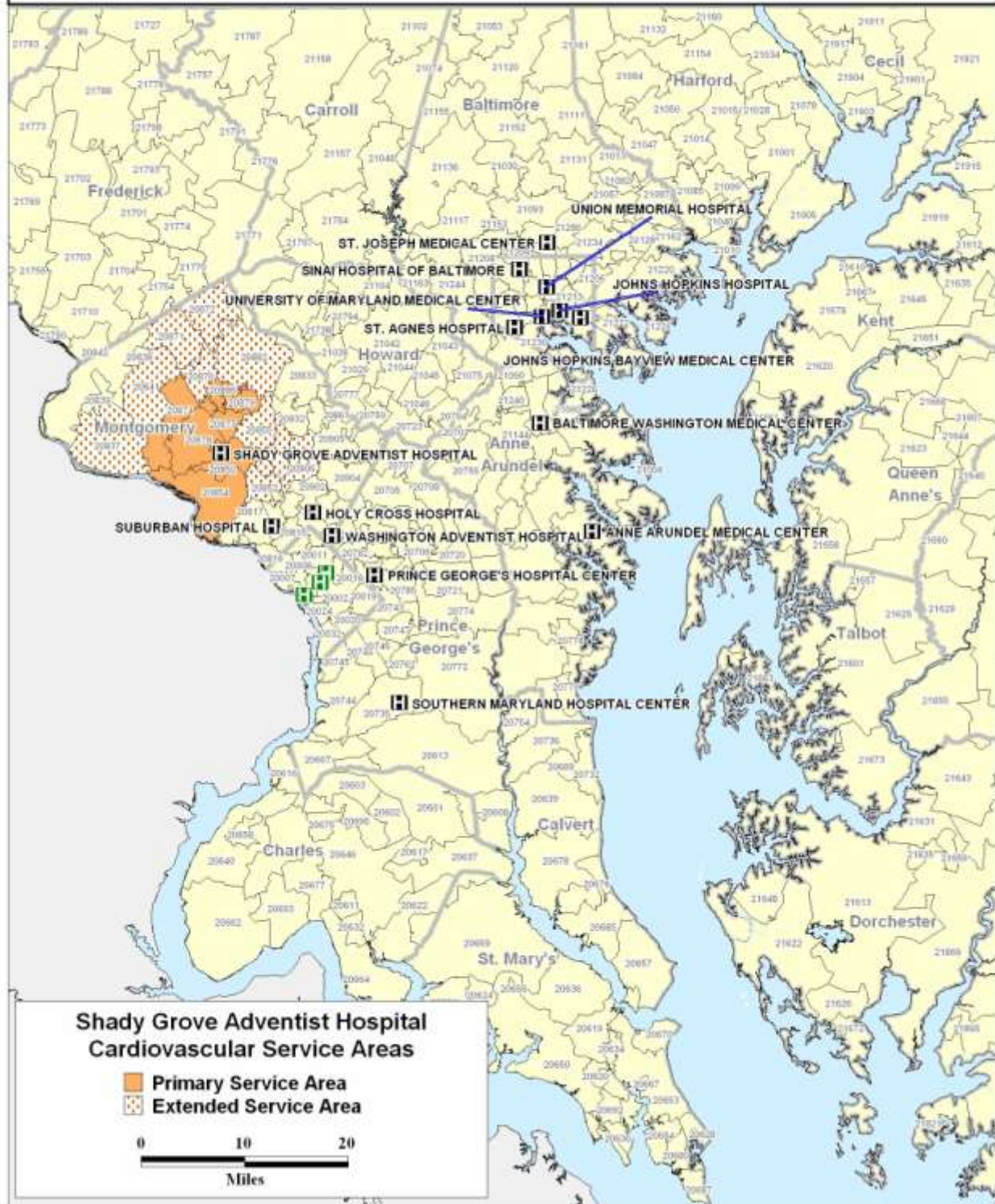
**Map 5. Primary and Extended Service Areas of Johns Hopkins Bayview Medical Center Based on Calendar Year 2006 Cardiovascular Inpatient Discharges.**



Source: Spatial Insights, Inc., Bethesda, MD



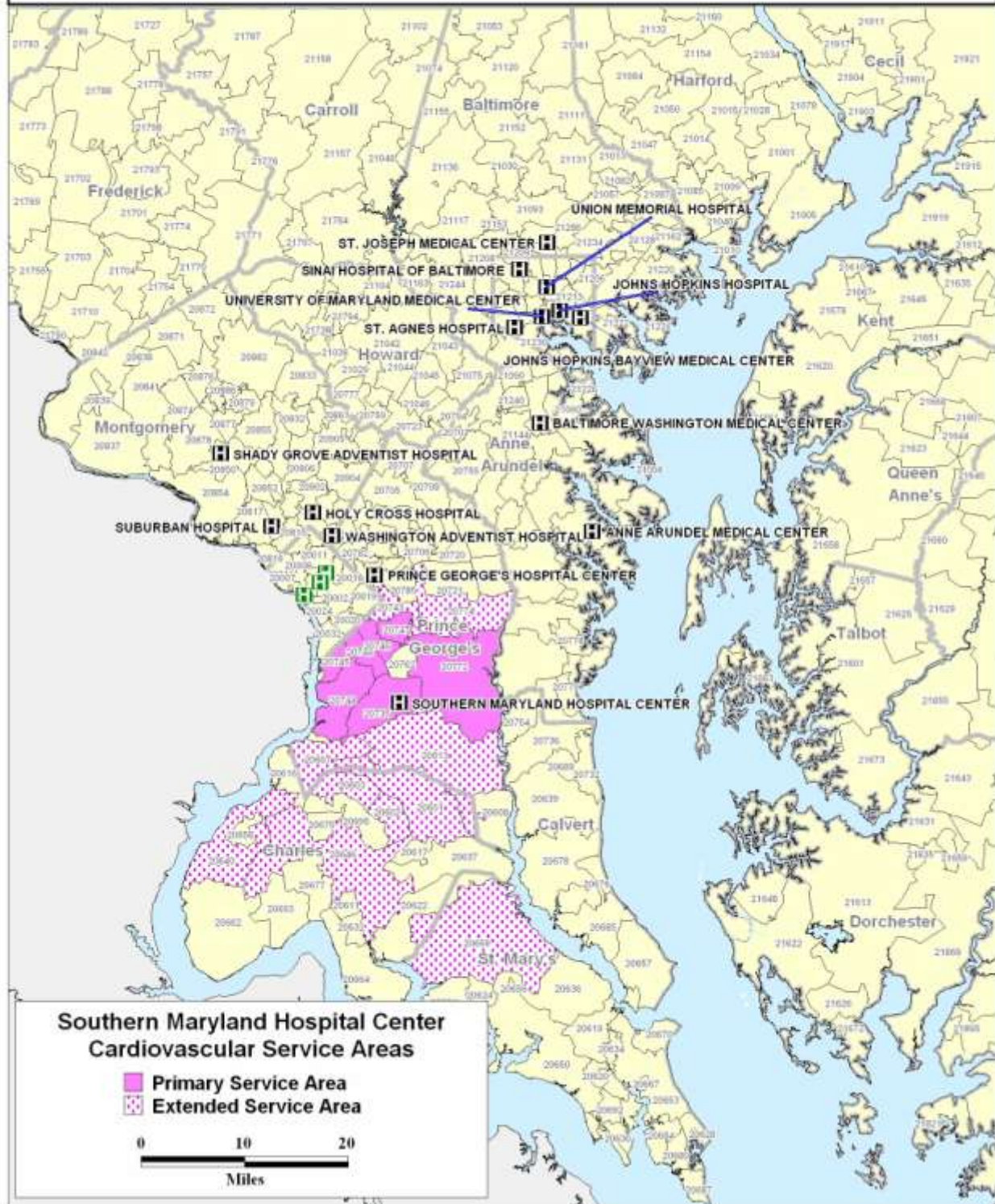
**Map 6. Primary and Extended Service Areas of Shady Grove Adventist Hospital  
Based on Calendar Year 2006 Cardiovascular Inpatient Discharges.**



Source: Spatial Insights, Inc., Bethesda, MD



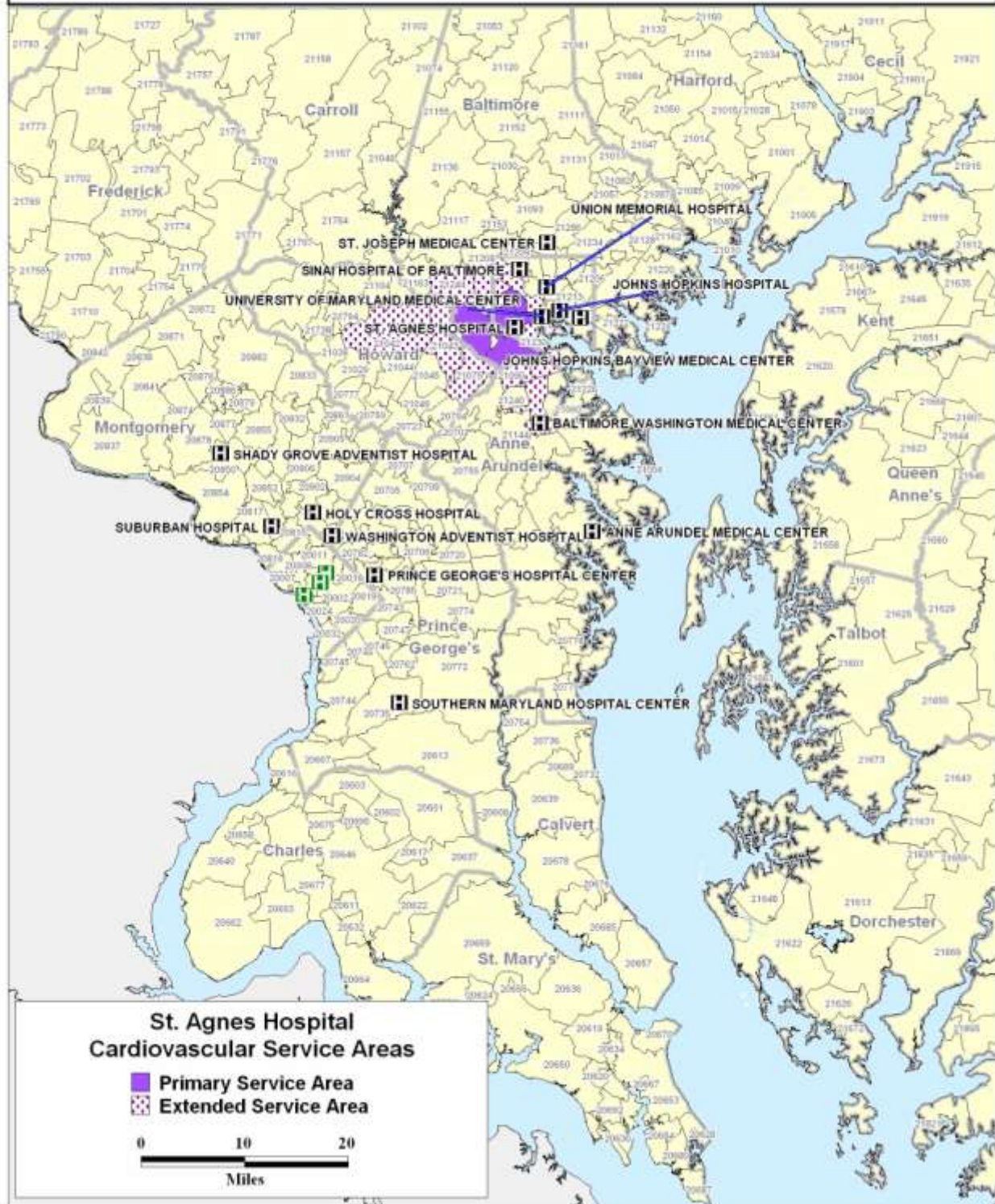
**Map 7. Primary and Extended Service Areas of Southern Maryland Hospital Center Based on Calendar Year 2006 Cardiovascular Inpatient Discharges.**



Source: Spatial Insights, Inc., Bethesda, MD



**Map 8. Primary and Extended Service Areas of St. Agnes Hospital Based on Calendar Year 2006 Cardiovascular Inpatient Discharges.**



Source: Spatial Insights, Inc., Bethesda, MD